

US3062102 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3062102

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

Participant ID

US3062102

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

US3062102

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 05 AUG 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Date of Birth (MMM yyyy)	(b) (6) 2000
Age	20
Age Units	YEARS
Age (Derived)	20
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

US3062102

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Date of Informed Consent (*dd MMM yyyy*) 05 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version
Amendment 1
Amendment 2
Amendment 3
Amendment 4
Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail
Withdrew Consent
Inclusion/Exclusion
Cohort Full
Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3062102

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Condition	ASTHMA (MODERATE)
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Condition	TYPE 2 DIABETES MELLITUS
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062102

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062102

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Condition	ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3062102

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 05 AUG 2020

Time of assessment (00:00-23:59) 15:20 (24 HR)

Vital Signs Date and Time (derived) 05 AUG 2020 15:20

Height (xxx.x) 180.0 cm

Weight (xxx.x) 131.0 kg

BMI (xxx.x) 40.43210 kg/m²

BMI units KG/M2

Temperature (xxx.x) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) ND - Not Done

Pulse units BPM

Respiratory Rate (xxx) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

05 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:25:25

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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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 05 AUG 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 03 May 2021 22:05:03

Generated On: 09 Jun 2021 15:01:07

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 143064

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

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

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

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

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

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

Liver Disease Yes
No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

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 (<i>dd MMM yyyy</i>)	05 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:20 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 15:20
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	99 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

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 (<i>dd MMM yyyy</i>)	05 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:58 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 16:58
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

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) 05 AUG 2020

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

Treatment Date and Time (derived) 05 AUG 2020 16:25

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 05 AUG 2020

Collection time (*00:00-23:59*) 15:32 (24 HR)

Collection date and time (derived) 05 AUG 2020 15:32

US3062102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Collection date (<i>dd MMM yyyy</i>)			05 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:34	05 AUG 2020 15:34
Nasopharyngeal Swab 2	No		

US3062102

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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 05 AUG 2020 16:59

PC Open Date & Time 05 AUG 2020 16:45

PC Close Date & Time 05 AUG 2020 19:15

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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 97.1 °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	05 AUG 2020 20:13
PC Open Date & Time	05 AUG 2020 20:10
PC Close Date & Time	06 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 AUG 2020 12:34
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 AUG 2020 17:21
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

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 08 AUG 2020 14:25

PC Open Date & Time 08 AUG 2020 12:00

PC Close Date & Time 09 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 AUG 2020 12:00
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 AUG 2020 12:00
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 AUG 2020 14:13
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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	05 AUG 2020 17:00
PC Open Date & Time	05 AUG 2020 16:45
PC Close Date & Time	05 AUG 2020 19:15

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

05 AUG 2020 20:13

PC Open Date & Time

05 AUG 2020 20:10

PC Close Date & Time

06 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 2

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 AUG 2020 12:34
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 AUG 2020 17:21

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 AUG 2020 14:25

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	09 AUG 2020 12:00
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 6

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 AUG 2020 12:00
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 7

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	11 AUG 2020 14:13
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

No

Yes

PC Time stamp	05 AUG 2020 17:00
PC Open Date & Time	05 AUG 2020 16:45
PC Close Date & Time	05 AUG 2020 19:15

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

No

Yes

PC Time stamp	05 AUG 2020 20:14
PC Open Date & Time	05 AUG 2020 20:10
PC Close Date & Time	06 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	06 AUG 2020 12:34
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	07 AUG 2020 17:21
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 14:26
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 12:01
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	10 AUG 2020 12:01
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

12 AUG 2020 17:28

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3062102

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 AUG 2020 17:28
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3062102

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

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 (<i>dd MMM yyyy</i>)	2 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	16:13 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 16:13
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	101 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

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 (<i>dd MMM yyyy</i>)	02 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	17:49 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 17:49
Temperature (<i>xxx.x</i>)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	94 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3062102

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

2 SEP 2020

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

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 SEP 2020

What was the treatment time? (00:00-23:59) 17:15 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 17:15

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

US3062102

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 2 SEP 2020

Collection time (*00:00-23:59*) 16:24 (24 HR)

Collection date and time (derived) 2 SEP 2020 16:24

US3062102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Collection date (<i>dd MMM yyyy</i>)			2 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	16:25	2 SEP 2020 16:25
Nasopharyngeal Swab 2	No		

US3062102

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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 99.3 °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 02 SEP 2020 17:46

PC Open Date & Time 02 SEP 2020 17:35

PC Close Date & Time 02 SEP 2020 20:05

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

PC Time Stamp 03 SEP 2020 07:00
PC Open Date & Time 02 SEP 2020 21:00
PC Close Date & Time 03 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	03 SEP 2020 12:13
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 SEP 2020 14:22
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

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

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 13:39
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 SEP 2020 14:33
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 SEP 2020 13:27
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	02 SEP 2020 17:47
PC Open Date & Time	02 SEP 2020 17:35
PC Close Date & Time	02 SEP 2020 20:05

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

03 SEP 2020 07:01

PC Open Date & Time

02 SEP 2020 21:00

PC Close Date & Time

03 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 2

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

03 SEP 2020 12:13

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	04 SEP 2020 14:23
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 4

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

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 5

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 SEP 2020 13:39
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 SEP 2020 14:34

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 SEP 2020 13:28

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

No

Yes

PC Time stamp	02 SEP 2020 17:47
PC Open Date & Time	02 SEP 2020 17:35
PC Close Date & Time	02 SEP 2020 20:05

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

No

Yes

PC Time stamp	03 SEP 2020 07:01
PC Open Date & Time	02 SEP 2020 21:00
PC Close Date & Time	03 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	03 SEP 2020 12:13
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 14:23
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 12:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 13:39
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 14:34
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 13:28
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3062102

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:25:25

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:25:26

Generated On: 09 Jun 2021 15:01:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 30 SEP 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT3

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:25:26

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:06 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 15:06
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3062102

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:25:26

Generated On: 09 Jun 2021 15:01:07

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.

US3062102

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:25:26

Generated On: 09 Jun 2021 15:01:07

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 30 SEP 2020

Collection time (*00:00-23:59*) 15:25 (24 HR)

Collection date and time (derived) 30 SEP 2020 15:25

US3062102

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:25:26

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 05 OCT 2020 08:00:13

Patient Cloud Open Date & Time 05 OCT 2020 00:01

Patient Cloud Close Date & Time 09 OCT 2020 23:59

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 12 OCT 2020 08:09:28

Patient Cloud Open Date & Time 12 OCT 2020 00:01

Patient Cloud Close Date & Time 16 OCT 2020 23:59

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 OCT 2020 12:24:08
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission 04 NOV 2020 10:11:32

Patient Cloud Open Date & Time 02 NOV 2020 00:01

Patient Cloud Close Date & Time 06 NOV 2020 23:59

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 03:56:32
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 NOV 2020 08:25:11
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 110

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

No

Yes

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

No

Yes

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

Date and time of submission 20 NOV 2020 09:10:01

Patient Cloud Open Date & Time 20 NOV 2020 00:01

Patient Cloud Close Date & Time 24 NOV 2020 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 117

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

No

Yes

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

No

Yes

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

Date and time of submission 27 NOV 2020 08:39:38

Patient Cloud Open Date & Time 27 NOV 2020 00:01

Patient Cloud Close Date & Time 01 DEC 2020 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 124

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

No

Yes

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

No

Yes

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

Date and time of submission 04 DEC 2020 00:01:38

Patient Cloud Open Date & Time 04 DEC 2020 00:01

Patient Cloud Close Date & Time 08 DEC 2020 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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	11 DEC 2020 10:42:25
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 18 DEC 2020 00:07:13

Patient Cloud Open Date & Time 18 DEC 2020 00:01

Patient Cloud Close Date & Time 22 DEC 2020 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 25 DEC 2020 01:00:56

Patient Cloud Open Date & Time 25 DEC 2020 00:01

Patient Cloud Close Date & Time 29 DEC 2020 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 JAN 2021 09:05:38
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 08 JAN 2021 12:11:02

Patient Cloud Open Date & Time 08 JAN 2021 00:01

Patient Cloud Close Date & Time 12 JAN 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 15 JAN 2021 09:57:44

Patient Cloud Open Date & Time 15 JAN 2021 00:01

Patient Cloud Close Date & Time 19 JAN 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 22 JAN 2021 15:15:43

Patient Cloud Open Date & Time 22 JAN 2021 00:01

Patient Cloud Close Date & Time 26 JAN 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 180

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

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 01:42:35
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 12 FEB 2021 07:22:49

Patient Cloud Open Date & Time 12 FEB 2021 00:01

Patient Cloud Close Date & Time 16 FEB 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 02:03:29
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 FEB 2021 14:11:57
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 12:00:30
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 14:28:54
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 MAR 2021 08:35:38
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 236

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

No

Yes

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

No

Yes

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

Date and time of submission 26 MAR 2021 21:52:17

Patient Cloud Open Date & Time 26 MAR 2021 00:01

Patient Cloud Close Date & Time 30 MAR 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 243

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

No

Yes

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

No

Yes

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

Date and time of submission 04 APR 2021 18:43:58

Patient Cloud Open Date & Time 02 APR 2021 00:01

Patient Cloud Close Date & Time 06 APR 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 250

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

No

Yes

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

No

Yes

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

Date and time of submission 09 APR 2021 21:20:00

Patient Cloud Open Date & Time 09 APR 2021 00:01

Patient Cloud Close Date & Time 13 APR 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 257

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

No

Yes

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

No

Yes

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

Date and time of submission 16 APR 2021 13:35:44

Patient Cloud Open Date & Time 16 APR 2021 00:01

Patient Cloud Close Date & Time 20 APR 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 264

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

No

Yes

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

No

Yes

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

Date and time of submission 23 APR 2021 19:36:41

Patient Cloud Open Date & Time 23 APR 2021 00:01

Patient Cloud Close Date & Time 27 APR 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 271

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

No

Yes

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

No

Yes

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

Date and time of submission 30 APR 2021 18:42:35

Patient Cloud Open Date & Time 30 APR 2021 00:01

Patient Cloud Close Date & Time 04 MAY 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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
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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2021 00:01
Patient Cloud Close Date & Time	25 MAY 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#) 08 JUN 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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
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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 348

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	06 AUG 2021 00:01
Patient Cloud Close Date & Time	10 AUG 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#) 17 AUG 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 439

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 446

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	29 OCT 2021 00:01
Patient Cloud Close Date & Time	02 NOV 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2021 00:01
Patient Cloud Close Date & Time	23 NOV 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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
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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	04 JAN 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	25 FEB 2022 00:01
Patient Cloud Close Date & Time	01 MAR 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#) 15 MAR 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	22 MAR 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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
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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 01 APR 2022 00:01

[Patient Cloud Close Date & Time](#) 05 APR 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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
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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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
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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 22 APR 2022 00:01

[Patient Cloud Close Date & Time](#) 26 APR 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	13 MAY 2022 00:01
Patient Cloud Close Date & Time	17 MAY 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2022 00:01
Patient Cloud Close Date & Time	31 MAY 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	07 JUN 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2022 00:01
Patient Cloud Close Date & Time	21 JUN 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

Patient Cloud Open Date & Time	24 JUN 2022 00:01
Patient Cloud Close Date & Time	28 JUN 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2022 00:01
Patient Cloud Close Date & Time	05 JUL 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	02 AUG 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 733

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	06 SEP 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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°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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#) 27 SEP 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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 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

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3062102

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:01:07

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 12:38:10

US3062102

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 20:56:51

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 20:56:51

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:30:45

Generated On: 09 Jun 2021 15:01:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 15 FEB 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT4

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:30:45

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	11:04 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 11:04
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 15:52:16

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

15 FEB 2021

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

US3062102

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 15 FEB 2021

Collection time (*00:00-23:59*) 11:13 (24 HR)

Collection date and time (derived) 15 FEB 2021 11:13

US3062102

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

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 _____

US3062102

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Date of Contact	23 FEB 2021
Time of Contact	13:33
Date and Time of Contact (derived)	23 FEB 2021 13:33
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input type="checkbox"/> Safety Call <input checked="" type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input 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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

Date 21 FEB 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 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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

Date 22 FEB 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 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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

Date 23 FEB 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 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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

	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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

Date	24 FEB 2021
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.7 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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 23 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

Date 25 FEB 2021

Assessment Not Done False

O2 Saturation 97 %

O2 Saturation Units %

Temperature 98.2 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

	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 FEB 2021

Assessment Not Done False

O2 Saturation 95 %

O2 Saturation Units %

Temperature 97.8 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

	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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

	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 FEB 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 type="radio"/>
Mild	<input checked="" type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Shortness of Breath

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

Difficulty Breathing

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

	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 FEB 2021

Assessment Not Done False

O2 Saturation 98 %

O2 Saturation Units %

Temperature 98.0 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

PRODUCTION RELEASE (v12.003
EAB) (1725)

347 of 3093

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

	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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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"/>

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

Date 01 MAR 2021

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 98.0 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:18:58

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Date of Visit 24 FEB 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes
No

Date of Test 24 FEB 2021

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes
No

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 0

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:01:07

Generate Next COVID-19 Assessment

Yes

No

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 FEB 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID SICKD1

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	15:42 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 15:42
Height (<i>xxx.x</i>)	180.0 cm
Weight (<i>xxx.x</i>)	131.0 kg
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3062102

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3062102

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection

24 FEB 2021

US3062102

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 14 JAN 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID UNBLND_DECIDE

US3062102

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 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>)	14 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

US3062102

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Height	
Weight	124.0 kg
BMI (xxx.x)	

US3062102

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Height	
Weight	124.0 kg
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)	14 JAN 2021
Time of assessment (00:00-23:59)	13:24 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 13:24
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	113 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3062102

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Height	
Weight	124.0 kg
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)	14 JAN 2021
Time of assessment (00:00-23:59)	15:07 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 15:07
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3062102

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3062102

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 14:35 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 14:35

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

US3062102

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 14 JAN 2021

Collection time (*00:00-23:59*) 13:29 (24 HR)

Collection date and time (derived) 14 JAN 2021 13:29

US3062102

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 14 JAN 2021

Collection time (*00:00 - 23:59*) 13:28

Collection Date and Time (derived) 14 JAN 2021 13:28

US3062102

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 15 FEB 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID OLD29

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

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 (<i>dd MMM yyyy</i>)	15 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	11:04 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 11:04
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

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 (<i>dd MMM yyyy</i>)	15 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	12:32 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 12:32
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3062102

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

15 FEB 2021

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

US3062102

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

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) 15 FEB 2021

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

Treatment Date and Time (derived) 15 FEB 2021 12:00

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

US3062102

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3062102

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:30:44

Generated On: 09 Jun 2021 15:01:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062102

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 10 MAR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID OLD57

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:17 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 10:17
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	95 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	93 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3062102

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

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.

US3062102

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 10 MAR 2021

Collection time (*00:00-23:59*) 10:27 (24 HR)

Collection date and time (derived) 10 MAR 2021 10:27

US3062102

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 20:56:50

Generated On: 09 Jun 2021 15:01:07

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

AEID _____

Adverse event _____ HYPERTENSION

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) _____ 8 FEB 2021

Start time (00:00-23:59) _____

AE start date and time (derived) _____

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) _____

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 _____

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

AEID USA-US090-2021-MRNA-1273-P30
1000009

Adverse event SUICIDAL IDEATION

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) 26 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 3 FEB 2021

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 True

Hospital Admission Date (dd MMM yyyy) 27 JAN 2021

Hospital Discharge Date (dd MMM yyyy) 3 FEB 2021

Admitted to ICU? Yes
No
Unknown

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EAB) (1725)

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

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
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

SUBJECT NOTIFIED SITE DURING OPEN LABEL DAY 29 VISIT OF A RECENT HOSPITALIZATION. THE SUBJECT WAS AT ER FOR AN UNRELATED EVENT ON 1/26/21, AND ENDED UP HAVING A MENTAL CONSULT. IT WAS DETERMINED THE SUBJECT WAS HAVING SUICIDAL THOUGHTS. THE SUBJECT WAS TRASFERED TO THE MENTAL HEALTH FLOOR AT A LOCAL HOSPITAL. ACCORDING TO THE SUBJECT, NO PHARMACOLOGICAL TREATMENT WAS ADMINISTERED, ONLY THERAPY. MEDICAL RECORDS REQUESTED FOR FURTHER INFORMATION. 2/17/2021 RECEIVED MEDICAL RECORDS FROM NMC HEALTH AND SALINA REGIONAL HEALTH CENTER. SUBJECT WAS SEEN IN ER FOR A DIFFERENT AE ON 1/26/2021. THE NEXT DAY 1/27/2021 SUBJECT WAS IN ER FOR SAE SUBJECT WAS DIAGNOSED WITH SCHIZOPHRENIA AND DRUG INDUCED PARANOIA DUE TO MARIJUANA. SUBJECT ATTEMPTED TO GET ADMITTED TO A LOCAL

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

MENTAL HEALTH FACILITY,
BUT THERE WERE NO OPEN
BEDS. SUBJECT WAS THEN
ADMITTED TO SALINA
REGIONAL MEDICAL CENTER
PSYCHIATRIC FLOOR. SUBJECT
WAS PRESCRIBED ZYPREXA 5
MG IN THE MORNING AND 10
MG AT BEDTIME. SUBJECT DID
NOT RECEIVE ANY NEW AES
AT SALINA REGIONAL
MEDICAL CENTER. SUBJECT
REPORTS NOT HAVING
SUICIDAL THOUGHTS SINCE
BEING DISCHARGED FROM THE
HOSPITAL.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

AEID

Adverse event

ALLERGIC REACTION TO
PEANUT BUTTER

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)

26 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

26 JAN 2021

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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 Apr 2021 20:30:28

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AEID	
Adverse event	NAUSEA
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)	26 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)	26 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

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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)	_____

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

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)	26 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)	26 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

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	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 (6)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

AEID	
Adverse event	SCHIZOPHRENIA
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)	27 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 02 Apr 2021 20:30:28

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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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 02 Apr 2021 20:30:28

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AEID

Adverse event

DRUG INDUCED PARANOIA

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)

27 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

3 FEB 2021

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 (7)

Data signed: (b) (4) 02 Apr 2021 20:30:28

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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	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 (8)

Data signed: (b) (4) 02 Apr 2021 20:30:28

Generated On: 09 Jun 2021 15:01:07

AEID	
Adverse event	COUGH
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)	21 FEB 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)	27 FEB 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 02 Apr 2021 20:30:28

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:30:29

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Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:30:29

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Name of Medication LEVOTHYROXINE

Prophylaxis Yes
No

Indication HYPOTHYROIDISM

Dose per administration 150

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:30:29

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Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2008

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication EFFEXOR

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 150

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

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) UN UNK 2017

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 14 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication BECLOMETHASONE

Prophylaxis Yes
No

Indication ASTHMA

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2012

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication ALBUTEROL

Prophylaxis Yes
No

Indication ASTHMA

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2012

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication METFORMIN

Prophylaxis Yes
No

Indication TYPE 2 DIABETES MELLITUS

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2012

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication ADDERALL

Prophylaxis Yes
No

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

Dose per administration 30

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Intraocular	<input type="checkbox"/>
Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN JUL 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 14 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication FOCALIN

Prophylaxis Yes
No

Indication ATTENTION DEFICIT
HYPERATCTIVITY DISORDER

Dose per administration 30

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 (7)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

	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)	15 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication EFFEXOR

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 75

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

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) 15 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication LISINOPRIL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 8 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Intramuscular	<input checked="" type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 28 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 28 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication ALLERGIC REACTION TO PEANUT BUTTER

Dose per administration 24

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

	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 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication ALLERGIC REACTION TO PEANUT BUTTER

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

	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) 27 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication ALLERGIC REACTION TO PEANUT BUTTER

Dose per administration 16

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

	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) 28 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 28 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication ALLERGIC REACTION TO
PEANUT BUTTER

Dose per administration 12

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

	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) 29 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 29 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication ALLERGIC REACTION TO PEANUT BUTTER

Dose per administration 8

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

	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) 30 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 30 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication ALLERGIC REACTION TO PEANUT BUTTER

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

	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) 31 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 31 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication BENADRYL

Prophylaxis Yes
No

Indication ALLERGIC REACTION TO
PEANUT BUTTER

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

	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 checked="" 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 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes
No

Indication ALLERGIC REACTION TO
PEANUT BUTTER

Dose per administration 125

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 26 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication PROVENTIL(ALBUTEROL
2.5MG/0.5ML)

Prophylaxis Yes
No

Indication ASTHMA

Dose per administration 2.5

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 26 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication PEPCID

Prophylaxis Yes
No

Indication ALLERGIC REACTION TO
PEANUT BUTTER

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 26 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication ZOFRAN

Prophylaxis Yes
No

Indication NAUSEA

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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US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

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 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication NORMAL SALINE

Prophylaxis Yes
No

Indication ALLERGIC REACTION TO PEANUT BUTTER

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify LITER

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 1 LITER/HOUR

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 26 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 26 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication ZYPREXA

Prophylaxis Yes
No

Indication SCHIZOPHRENIA

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
EAB) (1725)

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US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

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) 28 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication ZYPREXA

Prophylaxis Yes
No

Indication SCHIZOPHRENIA

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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US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

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) 28 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication SAPHRIS

Prophylaxis Yes
No

Indication SCHIZOPHRENIA

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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US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

	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 checked="" type="radio"/>

If route of administration is Other, specify	SUBLINGUAL
Start date (<i>dd MMM yyyy</i>)	27 JAN 2021
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	27 JAN 2021
Was this medication taken for solicited event?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 <input type="radio"/> 803 <input type="radio"/> 804 <input type="radio"/>

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication TRAZADONE

Prophylaxis Yes
No

Indication DEPRESSION

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 (26)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

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 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 27 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication VENLAFAXINE HCL

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 75

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 (27)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

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 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 27 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication TRAZODONE

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 100

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 (28)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

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 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Name of Medication BUSPIRONE

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 15

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 26 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:30:29

Generated On: 09 Jun 2021 15:01:07

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3062102

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:01:07

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

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/FEB/2021 09:28
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.	<input checked="" type="checkbox"/> True

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/FEB/2021 10:12
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

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	01/MAR/2021 12:14
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

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/MAR/2021 09:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/MAR/2021 14:51
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

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 20:30:30

Generated On: 09 Jun 2021 15:01:07

SAEID	USA-US090-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/MAR/2021 07:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3062102 (Prod: Alliance for Multispecialty Research, LLC)

US3062102

Form: Participant Creation

Generated On: 09 Jun 2021 15:01:07

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'US3062102'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 20:24:13

US3062102

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:36:42

US3062102

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 20:24:14

US3062102

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Clinic (Clinic)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:36:42

US3062102

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'SCRN'	System	05 Aug 2020 21:36:42

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered (b) (6) 2000'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 20:24:15

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '20'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:18:35

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'YEARS'	System	08 Aug 2020 15:18:35

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered '20'	System	05 Aug 2020 21:37:09

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Male (M)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:18:35

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:18:35

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '1'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:18:35

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:18:35

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:18:35

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '0'	Colton King (b) (4)	08 Aug 2020 15:18:35
	(b) (4)	

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '0'	Colton King (b) (4)	08 Aug 2020 15:18:35
	(b) (4)	

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:18:35

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:18:35

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:18:35

US3062102

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:01:07

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '0'	Colton King (b) (4)	08 Aug 2020 15:18:35
	(b) (4)	

US3062102

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '05 Aug 2020'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:37:09

US3062102

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'Aug 2020'	System	05 Aug 2020 21:37:09

US3062102

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered '2020'	System	05 Aug 2020 21:37:09

US3062102

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Amendment 1 (1)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:37:09

US3062102

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:37:09

US3062102

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:37:09

US3062102

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:37:09

US3062102

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:37:09

US3062102

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 20:24:14

US3062102

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:01:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered '1'	System	05 Aug 2020 21:37:17

US3062102

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:01:07

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:37:17

US3062102

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:01:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 20:51:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:51:39
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:04:35

US3062102

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 17:56:27
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 17:56:27
Data point term sent to Coder	System	08 Aug 2020 15:06:31
User entered 'Asthma (Moderate)'	Colton King (b) (4)	08 Aug 2020 15:05:53

US3062102

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'un UNK 2012'	Colton King (b) (4)	08 Aug 2020 15:05:53

US3062102

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:05:53

US3062102

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:05:53
	(b) (4)	

US3062102

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:05:53

US3062102

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:05:53

US3062102

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'Jan 2012'	System	08 Aug 2020 15:05:53

US3062102

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered '2012'	System	08 Aug 2020 15:05:53

US3062102

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:05:53

US3062102

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:01:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:05:53

US3062102

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Aug 2020 15:08:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 15:08:47
Data point term sent to Coder	System	08 Aug 2020 15:08:32
User entered 'Type 2 Diabetes Mellitus' reason for change: Data Entry Error	Colton King (b) (4) (b) (4)	08 Aug 2020 15:08:30
Data point term sent to Coder	System	08 Aug 2020 15:07:32
User entered 'Attention deficit hyperactivity disorder'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:06:42

US3062102

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'UN UNK 2012' reason for change: Data Entry Error	(b) (4) Colton King (b) (4)	08 Aug 2020 15:08:30
User entered 'un UNK 2014'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:06:42

US3062102

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:06:42

US3062102

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:06:42

US3062102

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:06:42

US3062102

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:06:42

US3062102

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'Jan 2012'	System	08 Aug 2020 15:08:30
User entered 'Jan 2014'	System	08 Aug 2020 15:06:42

US3062102

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered '2012'	System	08 Aug 2020 15:08:30
User entered '2014'	System	08 Aug 2020 15:06:42

US3062102

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:06:42

US3062102

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:01:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:06:42

US3062102

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 15:10:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 15:10:53
Data point term sent to Coder	System	08 Aug 2020 15:10:33
User entered 'Hypothyroidism'	Colton King (b) (4)	08 Aug 2020 15:09:34

US3062102

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'un UNK 2008'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:09:34

US3062102

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:09:34

US3062102

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:09:34

US3062102

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:09:34

US3062102

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '0'	Colton King (b) (4)	08 Aug 2020 15:09:34
	(b) (4)	

US3062102

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'Jan 2008'	System	08 Aug 2020 15:09:34

US3062102

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered '2008'	System	08 Aug 2020 15:09:34

US3062102

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:09:34

US3062102

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:01:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:09:34

US3062102

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	08 Aug 2020 15:13:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 15:13:41
Data point term sent to Coder	System	08 Aug 2020 15:12:33
User entered 'Obesity'	Colton King (b) (4)	08 Aug 2020 15:11:36

US3062102

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'un UNK 2008'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:11:36

US3062102

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:11:36

US3062102

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:11:36

US3062102

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:11:36

US3062102

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:11:36

US3062102

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'Jan 2008'	System	08 Aug 2020 15:11:36

US3062102

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered '2008'	System	08 Aug 2020 15:11:36

US3062102

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:11:36

US3062102

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:01:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:11:36

US3062102

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 15:13:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 15:13:41
Data point term sent to Coder	System	08 Aug 2020 15:12:34
User entered 'Attention Deficit Hyperactivity Disorder'	Colton King (b) (4)	08 Aug 2020 15:12:23

US3062102

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'un UNK 2014'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:12:23

US3062102

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:12:23

US3062102

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Aug 2020 15:12:23
	(b) (4)	

US3062102

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:12:23

US3062102

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:07

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '0'	Colton King (b) (4)	08 Aug 2020 15:12:23
	(b) (4)	

US3062102

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'Jan 2014'	System	08 Aug 2020 15:12:23

US3062102

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered '2014'	System	08 Aug 2020 15:12:23

US3062102

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:12:23

US3062102

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:01:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:12:23

US3062102

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:18:58
	(b) (4)	
User closed query 'please correct spelling' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 22:56:09
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 22:18:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 22:18:13
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 21:42:38
Query 'please correct spelling' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	12 Apr 2021 21:42:20
	(b) (4)	
Coding entries removed.	Riley King (b) (4)	12 Apr 2021 21:41:58
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	12 Apr 2021 21:41:58
	(b) (4)	
User entered 'depression' reason for change: Data Entry Error	Riley King (b) (4)	12 Apr 2021 21:41:58
	(b) (4)	
User opened query 'please correct spelling' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:51:07
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:21
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 15:13:35
User entered 'Depresstion'	Colton King (b) (4)	08 Aug 2020 15:12:54
	(b) (4)	

US3062102

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'un UNK 2017'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:12:54

US3062102

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:12:54

US3062102

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:12:54

US3062102

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty.	Colton King (b) (4)	08 Aug 2020 15:12:54
	(b) (4)	

US3062102

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:07

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:12:54

US3062102

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'Jan 2017'	System	08 Aug 2020 15:12:54

US3062102

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered '2017'	System	08 Aug 2020 15:12:54

US3062102

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:12:54

US3062102

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:01:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered empty.	System	08 Aug 2020 15:12:54

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:15:32

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '05 Aug 2020'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:15:32

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '15:20'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:15:32

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered '05 Aug 2020 15:20'	System	08 Aug 2020 15:15:32

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '180.0' cm	(b) (4) Colton King (b) (4)	08 Aug 2020 15:15:32
DataPoint set to visible.	(b) (4) System	05 Aug 2020 21:37:17

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '131.0' kg	(b) (4) Colton King (b) (4)	08 Aug 2020 15:15:32
DataPoint set to visible.	(b) (4) System	05 Aug 2020 21:37:17

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User closed query 'Per DM Re-query: Per response the randomization page is unlocked, kindly make the applicable changes.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:22:33
Query 'Per DM Re-query: Per response the randomization page is unlocked, kindly make the applicable changes.' answered with 'unable to update randomization page as page is locked. Please, unlock page or log line for obesity' (Site from DM).	marissa Mueller (b) (4)	15 Apr 2021 13:28:17
User opened query 'Per DM Re-query: Per response the randomization page is unlocked, kindly make the applicable changes.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 13:17:37
User closed query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 13:17:37
Query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' answered with 'Please unlock randomization ecrf page.' (Site from DM).	Justin Phillips (b) (4)	05 Apr 2021 18:24:28
User opened query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 03:07:34
Amendment Manager: User entered '40.43210'	System	16 Sep 2020 23:44:37
User entered '40.4'	System	08 Aug 2020 15:15:32
DataPoint set to visible.	System	05 Aug 2020 21:37:17

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'kg/m2'	System	08 Aug 2020 15:15:32
DataPoint set to visible.	System	05 Aug 2020 21:37:17

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:34
	(b) (4)	
User entered '98.2' F	Colton King (b) (4)	08 Aug 2020 15:15:32
	(b) (4)	

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:34
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	08 Aug 2020 15:15:32
	(b) (4)	

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:15:32

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:34
User entered '99'	(b) (4)	
	Colton King (b) (4)	08 Aug 2020 15:15:32
	(b) (4)	

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'bpm'	System	08 Aug 2020 15:15:32

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:34
User entered '14'	Colton King (b) (4)	08 Aug 2020 15:15:32
	(b) (4)	

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'breaths/min'	System	08 Aug 2020 15:15:32

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:34
User entered '126'	(b) (4)	
	Colton King (b) (4)	08 Aug 2020 15:15:32
	(b) (4)	

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'mmHg'	System	08 Aug 2020 15:15:32

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4) (b) (4)	26 Aug 2020 18:12:34
User entered '14'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:15:32

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User entered 'mmHg'	System	08 Aug 2020 15:15:32

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18

US3062102

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18

US3062102

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:58
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	08 Aug 2020 15:15:40
	(b) (4)	

US3062102

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Sep 2020 13:19:49
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		02 Sep 2020 22:32:57
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		01 Sep 2020 22:34:08
User entered '05 Aug 2020' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:58
User entered empty.	(b) (4)	
	Colton King (b) (4)	08 Aug 2020 15:15:40
	(b) (4)	

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	08 Aug 2020 15:19:10
	(b) (4)	

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	08 Aug 2020 15:19:10
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '0'	Colton King (b) (4)	08 Aug 2020 15:19:10
	(b) (4)	

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '0'	Colton King (b) (4)	08 Aug 2020 15:19:10
	(b) (4)	

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '1'	Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '0'	Colton King (b) (4)	08 Aug 2020 15:19:10
	(b) (4)	

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '0'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:01:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:18
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:19:10

US3062102

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:38:03

US3062102

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '05 Aug 2020'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:38:03

US3062102

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Clinic (Clinic)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:38:03

US3062102

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'VISIT1'	System	05 Aug 2020 21:38:03

US3062102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:52:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:57:28
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:48:24
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:40:54
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:12
Data hard unlocked.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 18:05:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	05 Aug 2020 20:54:24

US3062102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:52:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:57:28
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:48:24
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:40:54
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:12
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 18:05:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:21:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:21:43
User entered '143064' (non-conformant).	System	05 Aug 2020 20:54:24
	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 20:54:24

US3062102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:52:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:57:28
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:48:24
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:40:54
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:12
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 18:05:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 20:54:24

US3062102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:52:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:57:28
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:48:24
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:40:54
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:12
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 18:05:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:39:12

US3062102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:52:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:57:28
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:48:24
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:40:54
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:12
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 18:05:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	05 Aug 2020 21:39:12
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:52:11
User signature succeeded.	Richard Glover (b) (4)	03 May 2021 22:05:03
Data hard unlocked.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:57:28
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:48:24
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:40:54
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:12
User closed query 'Per DM : Screening visit, vital sign is recorded with BMI > 40Kg/m2, Randomization form has to be recorded with obesity' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 17:30:41
Query 'Per DM : Screening visit, vital sign is recorded with BMI > 40Kg/m2, Randomization form has to be recorded with obesity' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	29 Apr 2021 13:06:41
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	29 Apr 2021 13:05:03
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	29 Apr 2021 13:05:03
	(b) (4)	
User opened query 'Per DM : Screening visit, vital sign is recorded with BMI > 40Kg/m2, Randomization form has to be recorded with obesity' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 08:11:06
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 18:05:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	05 Aug 2020 21:39:12
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:52:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:57:28
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:48:24
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:40:54
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:12
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 18:05:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:39:12

US3062102

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:01:07

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:52:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:57:28
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:48:24
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:40:54
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:12
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 18:05:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	05 Aug 2020 21:39:12
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:46
User entered '180.0' cm	(b) (4)	
	Colton King (b) (4)	08 Aug 2020 15:17:35
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:46
User entered '131.0' kg	Colton King (b) (4)	08 Aug 2020 15:17:35
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:46
User entered '180.0' cm	Colton King (b) (4)	08 Aug 2020 15:17:35
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:46
	(b) (4)	
User entered '131.0' kg	Colton King (b) (4)	08 Aug 2020 15:17:35
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Aug 2020 15:17:35
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '05 Aug 2020'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '15:20'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered '05 Aug 2020 15:20'	System	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '98.2' F	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Oral (Oral)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '99'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'bpm'	System	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '14'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'breaths/min'	System	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '126'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'mmHg'	System	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '92'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'mmHg'	System	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:46
User entered '180.0' cm	Colton King (b) (4)	08 Aug 2020 15:17:35
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:12:46
	(b) (4)	
User entered '131.0' kg	Colton King (b) (4)	08 Aug 2020 15:17:35
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '05 Aug 2020'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 06:50:52
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Correct per protocol ' (Site from System).	Colton King (b) (4)	08 Aug 2020 15:18:12
	(b) (4)	
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		08 Aug 2020 15:17:35
User entered '16:58'	Colton King (b) (4)	08 Aug 2020 15:17:35
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered '05 Aug 2020 16:58'	System	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '98.1' F	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Oral (Oral)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '87'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'bpm'	System	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '17'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'breaths/min'	System	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '111'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'mmHg'	System	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '83'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'mmHg'	System	08 Aug 2020 15:17:35

US3062102

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:13:32
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Aug 2020 15:19:36
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 18:13:32
	(b) (4)	
User entered '05 Aug 2020'	Colton King (b) (4)	08 Aug 2020 15:19:36
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:39:48

US3062102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Riley King (b) (4)	05 Aug 2020 21:39:48

US3062102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Riley King (b) (4)	05 Aug 2020 21:39:48

US3062102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 21:39:48

US3062102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '05 Aug 2020'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:39:48

US3062102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '16:25'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:39:48

US3062102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered '05 Aug 2020 16:25'	System	05 Aug 2020 21:39:48

US3062102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) Riley King (b) (4) (b) (4)	05 Aug 2020 21:39:48

US3062102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'ONCE'	System	05 Aug 2020 21:39:48

US3062102

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 21:39:48

US3062102

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Aug 2020 15:20:26
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '05 Aug 2020'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:20:26

US3062102

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '15:32'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:20:26

US3062102

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered '05 Aug 2020 15:32'	System	08 Aug 2020 15:20:26

US3062102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	08 Aug 2020 15:21:08
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	08 Aug 2020 15:21:08
User entered '05 Aug 2020' reason for change: Data Entry Error	Colton King (b) (4)	08 Aug 2020 15:21:08
	(b) (4)	
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	08 Aug 2020 15:20:38
User entered empty.	Colton King (b) (4)	08 Aug 2020 15:20:38
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:20:38

US3062102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:20:38

US3062102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '15:34'	Colton King (b) (4)	08 Aug 2020 15:20:38
	(b) (4)	

US3062102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered '05 Aug 2020 15:34'	System	08 Aug 2020 15:21:08
User entered empty.	System	08 Aug 2020 15:20:38

US3062102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:20:38

US3062102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'No (N)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:20:38

US3062102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:20:38

US3062102

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered empty.	System	08 Aug 2020 15:20:38

US3062102

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:21:12

US3062102

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered '1'	System	08 Aug 2020 15:21:12

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T16:59:02', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0fabe55d-7f2e-4657-83b0-53e37b3da284' User entered 'Yes (Y)'	System	05 Aug 2020 21:59:39
	System	05 Aug 2020 21:59:39

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T16:59:09', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0fabe55d-7f2e-4657-83b0-53e37b3da284' User entered '98.1'	System	05 Aug 2020 21:59:39
	System	05 Aug 2020 21:59:39

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T16:59:32', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0fabe55d-7f2e-4657-83b0-53e37b3da284' User entered 'No (N)'	System	05 Aug 2020 21:59:39
	System	05 Aug 2020 21:59:39

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T16:59:36', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0fab55d-7f2e-4657-83b0-53e37b3da284' User entered '05 Aug 2020 16:59'	System	05 Aug 2020 21:59:39
	System	05 Aug 2020 21:59:39

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '05 Aug 2020 16:45'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '05 Aug 2020 19:15'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:13:24', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '9fee7b9b-95e8-4cb5-9ff2-c52b76ad45b0'	System	06 Aug 2020 01:13:41
User entered 'Yes (Y)'	System	06 Aug 2020 01:13:41

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:13:29', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '9fee7b9b-95e8-4cb5-9ff2-c52b76ad45b0' User entered '97.1'	System	06 Aug 2020 01:13:41
	System	06 Aug 2020 01:13:41

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:13:32', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '9fee7b9b-95e8-4cb5-9ff2-c52b76ad45b0'	System	06 Aug 2020 01:13:41
User entered 'No (N)'	System	06 Aug 2020 01:13:41

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:13:39', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '9fee7b9b-95e8-4cb5-9ff2-c52b76ad45b0' User entered '05 Aug 2020 20:13'	System	06 Aug 2020 01:13:41
	System	06 Aug 2020 01:13:41

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '05 Aug 2020 20:10'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 2'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '89f73015-161e-4def-8486-cecdeec8913f' User entered 'Yes (Y)'	System	06 Aug 2020 17:34:15
	System	06 Aug 2020 17:34:15

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:06', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '89f73015-161e-4def-8486-cecdeec8913f' User entered '97.5'	System	06 Aug 2020 17:34:15
	System	06 Aug 2020 17:34:15

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:10', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '89f73015-161e-4def-8486-cecdeec8913f' User entered 'No (N)'	System	06 Aug 2020 17:34:15
	System	06 Aug 2020 17:34:15

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:13', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '89f73015-161e-4def-8486-cecdeec8913f' User entered '06 Aug 2020 12:34'	System	06 Aug 2020 17:34:15
	System	06 Aug 2020 17:34:15

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 3'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:07', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd88d0849-a55a-4095-8016-984633cdbbd2'	System	07 Aug 2020 22:21:26
User entered 'Yes (Y)'	System	07 Aug 2020 22:21:26

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:18', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd88d0849-a55a-4095-8016-984633cdbbd2'	System	07 Aug 2020 22:21:26
User entered '97.5'	System	07 Aug 2020 22:21:26

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:20', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd88d0849-a55a-4095-8016-984633cdbbd2'	System	07 Aug 2020 22:21:26
User entered 'No (N)'	System	07 Aug 2020 22:21:26

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:23', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd88d0849-a55a-4095-8016-984633cdbbd2'	System	07 Aug 2020 22:21:26
User entered '07 Aug 2020 17:21'	System	07 Aug 2020 22:21:26

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 4'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:37', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '81469f66-11f7-4d9a-8c7d-c402e1c4e0cc' User entered 'Yes (Y)'	System	08 Aug 2020 19:25:48
	System	08 Aug 2020 19:25:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:43', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '81469f66-11f7-4d9a-8c7d-c402e1c4e0cc' User entered '98.0'	System	08 Aug 2020 19:25:48
	System	08 Aug 2020 19:25:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:44', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '81469f66-11f7-4d9a-8c7d-c402e1c4e0cc' User entered 'No (N)'	System	08 Aug 2020 19:25:48
	System	08 Aug 2020 19:25:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:47', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '81469f66-11f7-4d9a-8c7d-c402e1c4e0cc' User entered '08 Aug 2020 14:25'	System	08 Aug 2020 19:25:48
	System	08 Aug 2020 19:25:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 5'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:15', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '32c3fbd4-cc6d-4efd-8e1c-7a88098654ad' User entered 'Yes (Y)'	System	09 Aug 2020 17:00:33
	System	09 Aug 2020 17:00:33

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:23', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '32c3fbd4-cc6d-4efd-8e1c-7a88098654ad' User entered '98.6'	System	09 Aug 2020 17:00:33
	System	09 Aug 2020 17:00:33

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:24', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '32c3fbd4-cc6d-4efd-8e1c-7a88098654ad' User entered 'No (N)'	System	09 Aug 2020 17:00:33
	System	09 Aug 2020 17:00:33

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:27', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '32c3fbd4-cc6d-4efd-8e1c-7a88098654ad' User entered '09 Aug 2020 12:00'	System	09 Aug 2020 17:00:33
	System	09 Aug 2020 17:00:33

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 6'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:00:23', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5ea9c9a8-fe49-432f-b274-d07ab907addc' User entered 'Yes (Y)'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:00:42', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5ea9c9a8-fe49-432f-b274-d07ab907addc' User entered '97.2'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:00:44', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5ea9c9a8-fe49-432f-b274-d07ab907addc' User entered 'No (N)'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:00:49', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5ea9c9a8-fe49-432f-b274-d07ab907addc' User entered '10 Aug 2020 12:00'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 7'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:16', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3706382f-ddd8-44c8-aa08-1f2be764a716' User entered 'Yes (Y)'	System	11 Aug 2020 19:13:29
	System	11 Aug 2020 19:13:29

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:19', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3706382f-ddd8-44c8-aa08-1f2be764a716' User entered '98.8'	System	11 Aug 2020 19:13:29
	System	11 Aug 2020 19:13:29

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:21', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3706382f-ddd8-44c8-aa08-1f2be764a716'	System	11 Aug 2020 19:13:29
User entered 'No (N)'	System	11 Aug 2020 19:13:29

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:28', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3706382f-ddd8-44c8-aa08-1f2be764a716'	System	11 Aug 2020 19:13:29
User entered '11 Aug 2020 14:13'	System	11 Aug 2020 19:13:29

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T16:59:51', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f12898dd-24da-40aa-96ce-a2cde9c44df7'	System	05 Aug 2020 22:00:11
User entered 'None (1)'	System	05 Aug 2020 22:00:11

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T16:59:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f12898dd-24da-40aa-96ce-a2cde9c44df7'	System	05 Aug 2020 22:00:11
User entered 'No (N)'	System	05 Aug 2020 22:00:11

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f12898dd-24da-40aa-96ce-a2cde9c44df7'	System	05 Aug 2020 22:00:11
User entered 'No (N)'	System	05 Aug 2020 22:00:11

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:07', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f12898dd-24da-40aa-96ce-a2cde9c44df7'	System	05 Aug 2020 22:00:11
User entered 'None (1)'	System	05 Aug 2020 22:00:11

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:10', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f12898dd-24da-40aa-96ce-a2cde9c44df7' User entered '05 Aug 2020 17:00'	System	05 Aug 2020 22:00:11
	System	05 Aug 2020 22:00:11

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '05 Aug 2020 16:45'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '05 Aug 2020 19:15'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:13:43', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1851fc5c-97be-4ee7-95ae-35ae16b586f4' User entered 'None (1)'	System	06 Aug 2020 01:13:57
	System	06 Aug 2020 01:13:57

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:13:46', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1851fc5c-97be-4ee7-95ae-35ae16b586f4' User entered 'No (N)'	System	06 Aug 2020 01:13:57
	System	06 Aug 2020 01:13:57

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:13:48', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1851fc5c-97be-4ee7-95ae-35ae16b586f4' User entered 'No (N)'	System	06 Aug 2020 01:13:57
	System	06 Aug 2020 01:13:57

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:13:52', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1851fc5c-97be-4ee7-95ae-35ae16b586f4' User entered 'None (1)'	System	06 Aug 2020 01:13:57
	System	06 Aug 2020 01:13:57

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:13:55', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1851fc5c-97be-4ee7-95ae-35ae16b586f4' User entered '05 Aug 2020 20:13'	System	06 Aug 2020 01:13:57
	System	06 Aug 2020 01:13:57

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '05 Aug 2020 20:10'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 2'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:16', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1044ce28-6642-4821-9925-b565492fdf6d' User entered 'None (1)'	System	06 Aug 2020 17:34:26
	System	06 Aug 2020 17:34:26

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:17', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1044ce28-6642-4821-9925-b565492fdf6d'	System	06 Aug 2020 17:34:26
User entered 'No (N)'	System	06 Aug 2020 17:34:26

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:18', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1044ce28-6642-4821-9925-b565492fdf6d'	System	06 Aug 2020 17:34:26
User entered 'No (N)'	System	06 Aug 2020 17:34:26

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:20', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1044ce28-6642-4821-9925-b565492fdf6d'	System	06 Aug 2020 17:34:26
User entered 'None (1)'	System	06 Aug 2020 17:34:26

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:22', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1044ce28-6642-4821-9925-b565492fdf6d' User entered '06 Aug 2020 12:34'	System	06 Aug 2020 17:34:26
	System	06 Aug 2020 17:34:26

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 3'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:26', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7f517b56-521b-414b-9f03-c6b3cec34f33'	System	07 Aug 2020 22:21:37
User entered 'None (1)'	System	07 Aug 2020 22:21:37

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:28', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7f517b56-521b-414b-9f03-c6b3cec34f33'	System	07 Aug 2020 22:21:37
User entered 'No (N)'	System	07 Aug 2020 22:21:37

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:29', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7f517b56-521b-414b-9f03-c6b3cec34f33'	System	07 Aug 2020 22:21:37
User entered 'No (N)'	System	07 Aug 2020 22:21:37

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:31', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7f517b56-521b-414b-9f03-c6b3cec34f33'	System	07 Aug 2020 22:21:37
User entered 'None (1)'	System	07 Aug 2020 22:21:37

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:33', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7f517b56-521b-414b-9f03-c6b3cec34f33' User entered '07 Aug 2020 17:21'	System	07 Aug 2020 22:21:37
	System	07 Aug 2020 22:21:37

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 4'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:50', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e13f2eb8-fc38-47fc-a9f6-ab6dd76e362f' User entered 'None (1)'	System	08 Aug 2020 19:25:57
	System	08 Aug 2020 19:25:57

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:51', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e13f2eb8-fc38-47fc-a9f6-ab6dd76e362f' User entered 'No (N)'	System	08 Aug 2020 19:25:57
	System	08 Aug 2020 19:25:57

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:52', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e13f2eb8-fc38-47fc-a9f6-ab6dd76e362f' User entered 'No (N)'	System	08 Aug 2020 19:25:57
	System	08 Aug 2020 19:25:57

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:53', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e13f2eb8-fc38-47fc-a9f6-ab6dd76e362f' User entered 'None (1)'	System	08 Aug 2020 19:25:57
	System	08 Aug 2020 19:25:57

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:55', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e13f2eb8-fc38-47fc-a9f6-ab6dd76e362f' User entered '08 Aug 2020 14:25'	System	08 Aug 2020 19:25:57
	System	08 Aug 2020 19:25:57

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 5'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:31', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0ef2d302-6d94-4caf-854c-dc033990b37e' User entered 'None (1)'	System	09 Aug 2020 17:00:40
	System	09 Aug 2020 17:00:40

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:32', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0ef2d302-6d94-4caf-854c-dc033990b37e' User entered 'No (N)'	System	09 Aug 2020 17:00:40
	System	09 Aug 2020 17:00:40

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:34', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0ef2d302-6d94-4caf-854c-dc033990b37e' User entered 'No (N)'	System	09 Aug 2020 17:00:40
	System	09 Aug 2020 17:00:40

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:36', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0ef2d302-6d94-4caf-854c-dc033990b37e' User entered 'None (1)'	System	09 Aug 2020 17:00:40
	System	09 Aug 2020 17:00:40

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:38', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0ef2d302-6d94-4caf-854c-dc033990b37e' User entered '09 Aug 2020 12:00'	System	09 Aug 2020 17:00:40
	System	09 Aug 2020 17:00:40

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 6'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:00:52', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ad0ec87f-537c-4353-8c47-72da8bf1003'	System	10 Aug 2020 17:01:04
User entered 'None (1)'	System	10 Aug 2020 17:01:04

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:00:53', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ad0ec87f-537c-4353-8c47-72da8bf1003'	System	10 Aug 2020 17:01:04
User entered 'No (N)'	System	10 Aug 2020 17:01:04

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:00:55', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ad0ec87f-537c-4353-8c47-72da8bf1003'	System	10 Aug 2020 17:01:04
User entered 'No (N)'	System	10 Aug 2020 17:01:04

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:00:57', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ad0ec87f-537c-4353-8c47-72da8bf1003'	System	10 Aug 2020 17:01:04
User entered 'None (1)'	System	10 Aug 2020 17:01:04

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:00:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ad0ec87f-537c-4353-8c47-72da8bf1003' User entered '10 Aug 2020 12:00'	System	10 Aug 2020 17:01:04
	System	10 Aug 2020 17:01:04

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 7'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:31', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ed085cbe-a16b-4c40-b182-999c2386be56' User entered 'None (1)'	System	11 Aug 2020 19:13:41
	System	11 Aug 2020 19:13:41

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:33', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ed085cbe-a16b-4c40-b182-999c2386be56' User entered 'No (N)'	System	11 Aug 2020 19:13:41
	System	11 Aug 2020 19:13:41

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:34', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ed085cbe-a16b-4c40-b182-999c2386be56' User entered 'No (N)'	System	11 Aug 2020 19:13:41
	System	11 Aug 2020 19:13:41

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:36', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ed085cbe-a16b-4c40-b182-999c2386be56'	System	11 Aug 2020 19:13:41
User entered 'None (1)'	System	11 Aug 2020 19:13:41

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:38', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ed085cbe-a16b-4c40-b182-999c2386be56' User entered '11 Aug 2020 14:13'	System	11 Aug 2020 19:13:41
	System	11 Aug 2020 19:13:41

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:21', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1cd9ee97-b61a-425e-8d28-57abe4a06951' User entered 'None (0)'	System	05 Aug 2020 22:00:42
	System	05 Aug 2020 22:00:42

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:24', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1cd9ee97-b61a-425e-8d28-57abe4a06951' User entered 'None (0)'	System	05 Aug 2020 22:00:42
	System	05 Aug 2020 22:00:42

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:26', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1cd9ee97-b61a-425e-8d28-57abe4a06951' User entered 'None (0)'	System	05 Aug 2020 22:00:42
	System	05 Aug 2020 22:00:42

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:28', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1cd9ee97-b61a-425e-8d28-57abe4a06951' User entered 'None (0)'	System	05 Aug 2020 22:00:42
	System	05 Aug 2020 22:00:42

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:30', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1cd9ee97-b61a-425e-8d28-57abe4a06951' User entered 'None (0)'	System	05 Aug 2020 22:00:42
	System	05 Aug 2020 22:00:42

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:33', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1cd9ee97-b61a-425e-8d28-57abe4a06951' User entered 'None (0)'	System	05 Aug 2020 22:00:42
	System	05 Aug 2020 22:00:42

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:38', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1cd9ee97-b61a-425e-8d28-57abe4a06951' User entered 'No (N)'	System	05 Aug 2020 22:00:42
	System	05 Aug 2020 22:00:42

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T17:00:40', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1cd9ee97-b61a-425e-8d28-57abe4a06951' User entered '05 Aug 2020 17:00'	System	05 Aug 2020 22:00:42
	System	05 Aug 2020 22:00:42

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '05 Aug 2020 16:45'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '05 Aug 2020 19:15'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:13:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6eba9d2f-2182-4c36-9dbd-ffd666c75e3b' User entered 'None (0)'	System	06 Aug 2020 01:14:22
	System	06 Aug 2020 01:14:22

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:14:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6eba9d2f-2182-4c36-9dbd-ffd666c75e3b' User entered 'None (0)'	System	06 Aug 2020 01:14:22
	System	06 Aug 2020 01:14:22

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:14:04', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6eba9d2f-2182-4c36-9dbd-ffd666c75e3b' User entered 'None (0)'	System	06 Aug 2020 01:14:22
	System	06 Aug 2020 01:14:22

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:14:05', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6eba9d2f-2182-4c36-9dbd-ffd666c75e3b' User entered 'None (0)'	System	06 Aug 2020 01:14:22
	System	06 Aug 2020 01:14:22

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:14:07', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6eba9d2f-2182-4c36-9dbd-ffd666c75e3b' User entered 'None (0)'	System	06 Aug 2020 01:14:22
	System	06 Aug 2020 01:14:22

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:14:09', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6eba9d2f-2182-4c36-9dbd-ffd666c75e3b' User entered 'None (0)'	System	06 Aug 2020 01:14:22
	System	06 Aug 2020 01:14:22

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:14:15', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6eba9d2f-2182-4c36-9dbd-ffd666c75e3b' User entered 'No (N)'	System	06 Aug 2020 01:14:22
	System	06 Aug 2020 01:14:22

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-05T20:14:18', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6eba9d2f-2182-4c36-9dbd-ffd666c75e3b' User entered '05 Aug 2020 20:14'	System	06 Aug 2020 01:14:22
	System	06 Aug 2020 01:14:22

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '05 Aug 2020 20:10'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 2'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:24', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'aa00308e-f4fb-4b20-b726-451c98b159e7' User entered 'None (0)'	System	06 Aug 2020 17:34:36
	System	06 Aug 2020 17:34:36

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:26', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'aa00308e-f4fb-4b20-b726-451c98b159e7' User entered 'None (0)'	System	06 Aug 2020 17:34:36
	System	06 Aug 2020 17:34:36

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:27', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'aa00308e-f4fb-4b20-b726-451c98b159e7' User entered 'None (0)'	System	06 Aug 2020 17:34:36
	System	06 Aug 2020 17:34:36

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:28', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'aa00308e-f4fb-4b20-b726-451c98b159e7' User entered 'None (0)'	System	06 Aug 2020 17:34:36
	System	06 Aug 2020 17:34:36

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:29', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'aa00308e-f4fb-4b20-b726-451c98b159e7' User entered 'None (0)'	System	06 Aug 2020 17:34:36
	System	06 Aug 2020 17:34:36

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:31', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'aa00308e-f4fb-4b20-b726-451c98b159e7' User entered 'None (0)'	System	06 Aug 2020 17:34:36
	System	06 Aug 2020 17:34:36

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:32', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'aa00308e-f4fb-4b20-b726-451c98b159e7' User entered 'No (N)'	System	06 Aug 2020 17:34:36
	System	06 Aug 2020 17:34:36

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-06T12:34:34', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'aa00308e-f4fb-4b20-b726-451c98b159e7' User entered '06 Aug 2020 12:34'	System	06 Aug 2020 17:34:36
	System	06 Aug 2020 17:34:36

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 3'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:36', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb878869-78a4-44ec-a3e5-080af2a12843' User entered 'None (0)'	System	07 Aug 2020 22:21:48
	System	07 Aug 2020 22:21:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:37', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb878869-78a4-44ec-a3e5-080af2a12843' User entered 'None (0)'	System	07 Aug 2020 22:21:48
	System	07 Aug 2020 22:21:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:38', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb878869-78a4-44ec-a3e5-080af2a12843' User entered 'None (0)'	System	07 Aug 2020 22:21:48
	System	07 Aug 2020 22:21:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:39', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb878869-78a4-44ec-a3e5-080af2a12843' User entered 'None (0)'	System	07 Aug 2020 22:21:48
	System	07 Aug 2020 22:21:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:41', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb878869-78a4-44ec-a3e5-080af2a12843' User entered 'None (0)'	System	07 Aug 2020 22:21:48
	System	07 Aug 2020 22:21:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:42', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb878869-78a4-44ec-a3e5-080af2a12843' User entered 'None (0)'	System	07 Aug 2020 22:21:48
	System	07 Aug 2020 22:21:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:43', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb878869-78a4-44ec-a3e5-080af2a12843' User entered 'No (N)'	System	07 Aug 2020 22:21:48
	System	07 Aug 2020 22:21:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-07T17:21:45', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb878869-78a4-44ec-a3e5-080af2a12843' User entered '07 Aug 2020 17:21'	System	07 Aug 2020 22:21:48
	System	07 Aug 2020 22:21:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 4'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:58', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2e30ef17-003c-4fbf-b795-dee0333a81b5'	System	08 Aug 2020 19:26:23
User entered 'None (0)'	System	08 Aug 2020 19:26:23

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:25:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2e30ef17-003c-4fbf-b795-dee0333a81b5' User entered 'None (0)'	System	08 Aug 2020 19:26:23
	System	08 Aug 2020 19:26:23

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:26:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2e30ef17-003c-4fbf-b795-dee0333a81b5' User entered 'None (0)'	System	08 Aug 2020 19:26:23
	System	08 Aug 2020 19:26:23

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:26:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2e30ef17-003c-4fbf-b795-dee0333a81b5' User entered 'None (0)'	System	08 Aug 2020 19:26:23
	System	08 Aug 2020 19:26:23

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:26:04', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2e30ef17-003c-4fbf-b795-dee0333a81b5' User entered 'None (0)'	System	08 Aug 2020 19:26:23
	System	08 Aug 2020 19:26:23

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:26:05', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2e30ef17-003c-4fbf-b795-dee0333a81b5' User entered 'None (0)'	System	08 Aug 2020 19:26:23
	System	08 Aug 2020 19:26:23

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:26:14', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2e30ef17-003c-4fbf-b795-dee0333a81b5'	System	08 Aug 2020 19:26:23
User entered 'No (N)'	System	08 Aug 2020 19:26:23

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-08T14:26:20', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2e30ef17-003c-4fbf-b795-dee0333a81b5' User entered '08 Aug 2020 14:26'	System	08 Aug 2020 19:26:23
	System	08 Aug 2020 19:26:23

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 5'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:43', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '90035d2a-ebc5-4b12-a66b-fdfde41bf89a' User entered 'None (0)'	System	09 Aug 2020 17:01:05
	System	09 Aug 2020 17:01:05

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:48', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '90035d2a-ebc5-4b12-a66b-fdfde41bf89a' User entered 'None (0)'	System	09 Aug 2020 17:01:05
	System	09 Aug 2020 17:01:05

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:50', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '90035d2a-ebc5-4b12-a66b-fdfde41bf89a' User entered 'None (0)'	System	09 Aug 2020 17:01:05
	System	09 Aug 2020 17:01:05

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:53', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '90035d2a-ebc5-4b12-a66b-fdfde41bf89a' User entered 'None (0)'	System	09 Aug 2020 17:01:05
	System	09 Aug 2020 17:01:05

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:54', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '90035d2a-ebc5-4b12-a66b-fdfde41bf89a' User entered 'None (0)'	System	09 Aug 2020 17:01:05
	System	09 Aug 2020 17:01:05

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:56', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '90035d2a-ebc5-4b12-a66b-fdfde41bf89a'	System	09 Aug 2020 17:01:05
User entered 'None (0)'	System	09 Aug 2020 17:01:05

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:00:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '90035d2a-ebc5-4b12-a66b-fdfde41bf89a'	System	09 Aug 2020 17:01:05
User entered 'No (N)'	System	09 Aug 2020 17:01:05

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-09T12:01:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '90035d2a-ebc5-4b12-a66b-fdfde41bf89a' User entered '09 Aug 2020 12:01'	System	09 Aug 2020 17:01:05
	System	09 Aug 2020 17:01:05

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 6'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:01:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'bf2fe886-74b9-49da-b91f-7e38a7b68eb5' User entered 'None (0)'	System	10 Aug 2020 17:02:04
	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:01:13', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'bf2fe886-74b9-49da-b91f-7e38a7b68eb5'	System	10 Aug 2020 17:02:04
User entered 'Some interference with activity (2)'	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:01:17', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'bf2fe886-74b9-49da-b91f-7e38a7b68eb5' User entered 'None (0)'	System	10 Aug 2020 17:02:04
	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:01:19', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'bf2fe886-74b9-49da-b91f-7e38a7b68eb5' User entered 'None (0)'	System	10 Aug 2020 17:02:04
	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:01:34', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'bf2fe886-74b9-49da-b91f-7e38a7b68eb5' User entered 'None (0)'	System	10 Aug 2020 17:02:04
	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:01:41', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'bf2fe886-74b9-49da-b91f-7e38a7b68eb5' User entered 'None (0)'	System	10 Aug 2020 17:02:04
	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:01:51', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'bf2fe886-74b9-49da-b91f-7e38a7b68eb5'	System	10 Aug 2020 17:02:04
User entered 'No (N)'	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-10T12:01:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'bf2fe886-74b9-49da-b91f-7e38a7b68eb5' User entered '10 Aug 2020 12:01'	System	10 Aug 2020 17:02:04
	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 7'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:41', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5971c676-1a40-4453-8378-fa00e2299691' User entered 'None (0)'	System	11 Aug 2020 19:14:02
	System	11 Aug 2020 19:14:02

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:43', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5971c676-1a40-4453-8378-fa00e2299691'	System	11 Aug 2020 19:14:02
User entered 'No interference with activity (1)'	System	11 Aug 2020 19:14:02

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:45', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5971c676-1a40-4453-8378-fa00e2299691' User entered 'None (0)'	System	11 Aug 2020 19:14:02
	System	11 Aug 2020 19:14:02

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:46', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5971c676-1a40-4453-8378-fa00e2299691' User entered 'None (0)'	System	11 Aug 2020 19:14:02
	System	11 Aug 2020 19:14:02

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:48', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5971c676-1a40-4453-8378-fa00e2299691' User entered 'None (0)'	System	11 Aug 2020 19:14:02
	System	11 Aug 2020 19:14:02

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:49', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5971c676-1a40-4453-8378-fa00e2299691' User entered 'None (0)'	System	11 Aug 2020 19:14:02
	System	11 Aug 2020 19:14:02

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

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 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:55', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5971c676-1a40-4453-8378-fa00e2299691' User entered 'No (N)'	System	11 Aug 2020 19:14:02
	System	11 Aug 2020 19:14:02

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-11T14:13:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5971c676-1a40-4453-8378-fa00e2299691' User entered '11 Aug 2020 14:13'	System	11 Aug 2020 19:14:02
	System	11 Aug 2020 19:14:02

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
Data entry locked.	System	10 Aug 2020 17:02:04
User entered 'Day 8'	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:01:07

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-12T17:28:42', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '92528fc0-09a6-4e7c-9e3c-a825197f5956'	System	12 Aug 2020 22:28:48
User entered 'None (0)'	System	12 Aug 2020 22:28:48

US3062102

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-12T17:28:46', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '92528fc0-09a6-4e7c-9e3c-a825197f5956' User entered '12 Aug 2020 17:28'	System	12 Aug 2020 22:28:48
	System	12 Aug 2020 22:28:48

US3062102

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	10 Aug 2020 17:02:04
User entered 'Day 8'	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-12T17:28:49', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '61367f9d-b57d-42bb-8b98-6e57291867cd' User entered 'No (N)'	System	12 Aug 2020 22:28:55
	System	12 Aug 2020 22:28:55

US3062102

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-08-12T17:28:53', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '61367f9d-b57d-42bb-8b98-6e57291867cd' User entered '12 Aug 2020 17:28'	System	12 Aug 2020 22:28:55
	System	12 Aug 2020 22:28:55

US3062102

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:02:04

US3062102

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:02:04

US3062102

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	14 Aug 2020 17:29:18
	(b) (4)	

US3062102

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '13 Aug 2020'	(b) (4) Janna Martinez (b) (4)	14 Aug 2020 17:29:18
	(b) (4)	

US3062102

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	14 Aug 2020 17:29:18
	(b) (4)	

US3062102

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Janna Martinez (b) (4)	14 Aug 2020 17:29:18

US3062102

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	14 Aug 2020 17:29:09
	(b) (4)	

US3062102

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered '1'	System	14 Aug 2020 17:29:09

US3062102

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	Janna Martinez (b) (4)	20 Aug 2020 16:24:54

US3062102

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '20 Aug 2020'	Janna Martinez (b) (4)	20 Aug 2020 16:24:54

US3062102

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	20 Aug 2020 16:24:54

US3062102

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	20 Aug 2020 16:24:54
	(b) (4)	

US3062102

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 16:24:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 16:24:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Janna Martinez (b) (4)	20 Aug 2020 16:24:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 16:24:22
User entered empty.	Janna Martinez (b) (4)	20 Aug 2020 16:24:22
	(b) (4)	

US3062102

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:46:12
User entered '1'	System	20 Aug 2020 16:24:25
User entered empty.	System	20 Aug 2020 16:24:22

US3062102

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:53:04
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	27 Aug 2020 19:35:26
	(b) (4)	

US3062102

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:53:04
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '27 Aug 2020'	(b) (4) Janna Martinez (b) (4)	27 Aug 2020 19:35:26
	(b) (4)	

US3062102

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:53:04
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	27 Aug 2020 19:35:26

US3062102

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:53:04
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered empty.	(b) (4) Janna Martinez (b) (4)	27 Aug 2020 19:35:26
	(b) (4)	

US3062102

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:53:04
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	27 Aug 2020 19:35:28
	(b) (4)	

US3062102

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:53:04
User entered '1'	System	27 Aug 2020 19:35:28

US3062102

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 11:23:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry Henning (b) (4)	02 Sep 2020 22:32:57
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'CRF opened in error.' (Site from System).	Sherry Henning (b) (4)	01 Sep 2020 22:34:33
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 22:34:08
User entered empty; reason for change Data Entry Error	Sherry Henning (b) (4)	01 Sep 2020 22:34:08
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Sep 2020 22:33:20
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '2 Sep 2020' reason for change: Data Entry Error	Sherry Henning (b) (4)	02 Sep 2020 22:32:57
	(b) (4)	
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Sep 2020 22:34:08
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	01 Sep 2020 22:34:08
User entered empty; reason for change Data Entry Error	Sherry Henning (b) (4)	01 Sep 2020 22:34:08
	(b) (4)	
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Sep 2020 22:33:20
User entered '1 Sep 2020'	Sherry Henning (b) (4)	01 Sep 2020 22:33:20
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[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 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Sherry Henning (b) (4)	02 Sep 2020 22:32:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sherry Henning (b) (4)	01 Sep 2020 22:34:08
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	01 Sep 2020 22:33:20
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'VISIT2'	System	02 Sep 2020 22:32:57
User entered empty.	System	01 Sep 2020 22:34:08
User entered 'VISIT2'	System	01 Sep 2020 22:33:20

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '2 Sep 2020'	(b) (4) Sherry Henning (b) (4)	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '16:13'	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '2 Sep 2020 16:13'	System	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '98.5' F	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered empty.	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered '101'	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'bpm'	System	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '16'	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'breaths/min'	System	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '109'	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'mmHg'	System	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '85'	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'mmHg'	System	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Sep 2020 20:02:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:02:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Janna Martinez (b) (4)	03 Sep 2020 20:02:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 22:22:34
User entered empty.	System	02 Sep 2020 22:22:34
	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 20:02:28
User entered '02 Sep 2020' reason for change: Data Entry Error	Janna Martinez (b) (4)	03 Sep 2020 20:02:28
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 20:02:11
User entered '03 Sep 2020' reason for change: Data Entry Error	Janna Martinez (b) (4)	03 Sep 2020 20:02:11
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '17:49' reason for change: Data Entry Error	Janna Martinez (b) (4)	03 Sep 2020 20:02:11
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '02 Sep 2020 17:49'	System	03 Sep 2020 20:02:28
User entered '03 Sep 2020 17:49'	System	03 Sep 2020 20:02:11
User entered empty.	System	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered '99.3' F reason for change: Data Entry Error	Janna Martinez (b) (4) (b) (4)	03 Sep 2020 20:02:11
User entered empty.	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered 'Oral (Oral)' reason for change: Data Entry Error	Janna Martinez (b) (4) (b) (4)	03 Sep 2020 20:02:11
User entered empty.	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered empty.	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered '94' reason for change: Data Entry Error	Janna Martinez (b) (4) (b) (4)	03 Sep 2020 20:02:11
User entered empty.	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'bpm'	System	03 Sep 2020 20:02:11
User entered empty.	System	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '16' reason for change: Data Entry Error	Janna Martinez (b) (4)	03 Sep 2020 20:02:11
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'breaths/min'	System	03 Sep 2020 20:02:11
User entered empty.	System	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '91' reason for change: Data Entry Error	Janna Martinez (b) (4)	03 Sep 2020 20:02:11
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'mmHg'	System	03 Sep 2020 20:02:11
User entered empty.	System	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '61' reason for change: Data Entry Error	Janna Martinez (b) (4)	03 Sep 2020 20:02:11
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	02 Sep 2020 22:22:34
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'mmHg'	System	03 Sep 2020 20:02:11
User entered empty.	System	02 Sep 2020 22:22:34

US3062102

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	02 Sep 2020 22:22:45
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '2 Sep 2020'	Sherry Henning (b) (4)	02 Sep 2020 22:22:45
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	02 Sep 2020 22:23:17
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	02 Sep 2020 22:23:17
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered empty.	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:23:17

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 22:23:17

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered '2 Sep 2020'	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:23:17

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '17:15'	Sherry Henning (b) (4)	02 Sep 2020 22:23:17
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '2 Sep 2020 17:15'	System	02 Sep 2020 22:23:17

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered 'Left Arm (LEFT ARM)'	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:23:17

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'ONCE'	System	02 Sep 2020 22:23:17

US3062102

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 22:23:17

US3062102

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	02 Sep 2020 22:23:45
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '2 Sep 2020'	Sherry Henning (b) (4)	02 Sep 2020 22:23:45
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '16:24'	Sherry Henning (b) (4)	02 Sep 2020 22:23:45
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '2 Sep 2020 16:24'	System	02 Sep 2020 22:23:45

US3062102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '2 Sep 2020'	Sherry Henning (b) (4)	02 Sep 2020 22:24:01
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:24:01

US3062102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	02 Sep 2020 22:24:01
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '16:25'	Sherry Henning (b) (4)	02 Sep 2020 22:24:01
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:01:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '2 Sep 2020 16:25'	System	02 Sep 2020 22:24:01

US3062102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry Henning (b) (4) (b) (4)	02 Sep 2020 22:24:01

US3062102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	02 Sep 2020 22:24:01
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	02 Sep 2020 22:24:01
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:01:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered empty.	System	02 Sep 2020 22:24:01

US3062102

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	03 Sep 2020 19:40:35
	(b) (4)	

US3062102

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '1'	System	03 Sep 2020 19:40:35

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:46:18', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb06a124-e62a-4b9f-b8e3-74ca85591b1d' User entered 'Yes (Y)'	System	02 Sep 2020 22:46:46
	System	02 Sep 2020 22:46:46

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:46:29', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb06a124-e62a-4b9f-b8e3-74ca85591b1d' User entered '99.3'	System	02 Sep 2020 22:46:46
	System	02 Sep 2020 22:46:46

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:46:37', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb06a124-e62a-4b9f-b8e3-74ca85591b1d' User entered 'No (N)'	System	02 Sep 2020 22:46:46
	System	02 Sep 2020 22:46:46

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:46:44', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'cb06a124-e62a-4b9f-b8e3-74ca85591b1d' User entered '02 Sep 2020 17:46'	System	02 Sep 2020 22:46:46
	System	02 Sep 2020 22:46:46

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '02 Sep 2020 17:35'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '02 Sep 2020 20:05'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:00:46', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '82e7e18a-cfb6-4326-89b5-80612206824b' User entered 'Yes (Y)'	System	03 Sep 2020 12:00:56
	System	03 Sep 2020 12:00:56

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:00:50', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '82e7e18a-cfb6-4326-89b5-80612206824b' User entered '98.5'	System	03 Sep 2020 12:00:56
	System	03 Sep 2020 12:00:56

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:00:52', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '82e7e18a-cfb6-4326-89b5-80612206824b' User entered 'No (N)'	System	03 Sep 2020 12:00:56
	System	03 Sep 2020 12:00:56

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:00:54', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '82e7e18a-cfb6-4326-89b5-80612206824b' User entered '03 Sep 2020 07:00'	System	03 Sep 2020 12:00:56
	System	03 Sep 2020 12:00:56

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '02 Sep 2020 21:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 2'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:17', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f6a29193-85b5-4a9c-b00c-a1e5175ec361' User entered 'Yes (Y)'	System	03 Sep 2020 17:13:29
	System	03 Sep 2020 17:13:29

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:21', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f6a29193-85b5-4a9c-b00c-a1e5175ec361' User entered '99.5'	System	03 Sep 2020 17:13:29
	System	03 Sep 2020 17:13:29

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:23', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f6a29193-85b5-4a9c-b00c-a1e5175ec361'	System	03 Sep 2020 17:13:29
User entered 'No (N)'	System	03 Sep 2020 17:13:29

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:26', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f6a29193-85b5-4a9c-b00c-a1e5175ec361' User entered '03 Sep 2020 12:13'	System	03 Sep 2020 17:13:29
	System	03 Sep 2020 17:13:29

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 3'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:22:29', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'b8123dc7-496c-4bd4-8138-49d03af690f6' User entered 'Yes (Y)'	System	04 Sep 2020 19:22:50
	System	04 Sep 2020 19:22:50

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:22:38', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'b8123dc7-496c-4bd4-8138-49d03af690f6' User entered '98.5'	System	04 Sep 2020 19:22:50
	System	04 Sep 2020 19:22:50

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:22:44', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'b8123dc7-496c-4bd4-8138-49d03af690f6'	System	04 Sep 2020 19:22:50
User entered 'No (N)'	System	04 Sep 2020 19:22:50

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:22:48', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'b8123dc7-496c-4bd4-8138-49d03af690f6' User entered '04 Sep 2020 14:22'	System	04 Sep 2020 19:22:50
	System	04 Sep 2020 19:22:50

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 4'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:00:32', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '01d8db9d-9ef0-40cf-8b3b-c5c72a8789ca' User entered 'Yes (Y)'	System	05 Sep 2020 17:00:50
	System	05 Sep 2020 17:00:50

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:00:39', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '01d8db9d-9ef0-40cf-8b3b-c5c72a8789ca' User entered '97.5'	System	05 Sep 2020 17:00:50
	System	05 Sep 2020 17:00:50

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:00:43', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '01d8db9d-9ef0-40cf-8b3b-c5c72a8789ca' User entered 'No (N)'	System	05 Sep 2020 17:00:50
	System	05 Sep 2020 17:00:50

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:00:46', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '01d8db9d-9ef0-40cf-8b3b-c5c72a8789ca' User entered '05 Sep 2020 12:00'	System	05 Sep 2020 17:00:50
	System	05 Sep 2020 17:00:50

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 5'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:32', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '975c3431-2762-48e1-ae21-3d8db595bea4' User entered 'Yes (Y)'	System	06 Sep 2020 18:39:42
	System	06 Sep 2020 18:39:42

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:36', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '975c3431-2762-48e1-ae21-3d8db595bea4' User entered '98.6'	System	06 Sep 2020 18:39:42
	System	06 Sep 2020 18:39:42

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:38', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '975c3431-2762-48e1-ae21-3d8db595bea4'	System	06 Sep 2020 18:39:42
User entered 'No (N)'	System	06 Sep 2020 18:39:42

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:39', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '975c3431-2762-48e1-ae21-3d8db595bea4' User entered '06 Sep 2020 13:39'	System	06 Sep 2020 18:39:42
	System	06 Sep 2020 18:39:42

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 6'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:33:24', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e107442d-a98c-4018-8410-6fcef82703e7' User entered 'Yes (Y)'	System	07 Sep 2020 19:33:57
	System	07 Sep 2020 19:33:57

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:33:39', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e107442d-a98c-4018-8410-6fcef82703e7' User entered '97.1'	System	07 Sep 2020 19:33:57
	System	07 Sep 2020 19:33:57

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:33:15', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e107442d-a98c-4018-8410-6fcef82703e7' User entered 'No (N)'	System	07 Sep 2020 19:33:57
	System	07 Sep 2020 19:33:57

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:33:54', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e107442d-a98c-4018-8410-6fcef82703e7' User entered '07 Sep 2020 14:33'	System	07 Sep 2020 19:33:57
	System	07 Sep 2020 19:33:57

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 7'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:27:49', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'c3df286b-93bb-45d6-b009-fb3cf5e14e97'	System	08 Sep 2020 18:28:01
User entered 'Yes (Y)'	System	08 Sep 2020 18:28:01

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:27:54', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'c3df286b-93bb-45d6-b009-fb3cf5e14e97'	System	08 Sep 2020 18:28:01
User entered '98.5'	System	08 Sep 2020 18:28:01

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:27:56', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'c3df286b-93bb-45d6-b009-fb3cf5e14e97'	System	08 Sep 2020 18:28:01
User entered 'No (N)'	System	08 Sep 2020 18:28:01

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:27:57', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'c3df286b-93bb-45d6-b009-fb3cf5e14e97'	System	08 Sep 2020 18:28:01
User entered '08 Sep 2020 13:27'	System	08 Sep 2020 18:28:01

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:46:56', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '91f0f3c6-e179-4465-a4ff-3bdc78350c75'	System	02 Sep 2020 22:47:19
User entered 'None (1)'	System	02 Sep 2020 22:47:19

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '91f0f3c6-e179-4465-a4ff-3bdc78350c75'	System	02 Sep 2020 22:47:19
User entered 'No (N)'	System	02 Sep 2020 22:47:19

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:13', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '91f0f3c6-e179-4465-a4ff-3bdc78350c75'	System	02 Sep 2020 22:47:19
User entered 'No (N)'	System	02 Sep 2020 22:47:19

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:16', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '91f0f3c6-e179-4465-a4ff-3bdc78350c75'	System	02 Sep 2020 22:47:19
User entered 'None (1)'	System	02 Sep 2020 22:47:19

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:18', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '91f0f3c6-e179-4465-a4ff-3bdc78350c75'	System	02 Sep 2020 22:47:19
User entered '02 Sep 2020 17:47'	System	02 Sep 2020 22:47:19

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '02 Sep 2020 17:35'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '02 Sep 2020 20:05'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:04', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '090bb73f-e059-4586-b616-ed029d256f78'	System	03 Sep 2020 12:01:16
User entered 'None (1)'	System	03 Sep 2020 12:01:16

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:06', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '090bb73f-e059-4586-b616-ed029d256f78' User entered 'No (N)'	System	03 Sep 2020 12:01:16
	System	03 Sep 2020 12:01:16

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:08', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '090bb73f-e059-4586-b616-ed029d256f78' User entered 'No (N)'	System	03 Sep 2020 12:01:16
	System	03 Sep 2020 12:01:16

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:09', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '090bb73f-e059-4586-b616-ed029d256f78'	System	03 Sep 2020 12:01:16
User entered 'None (1)'	System	03 Sep 2020 12:01:16

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:11', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '090bb73f-e059-4586-b616-ed029d256f78' User entered '03 Sep 2020 07:01'	System	03 Sep 2020 12:01:16
	System	03 Sep 2020 12:01:16

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '02 Sep 2020 21:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 2'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:29', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4f740ee5-69e3-4cd2-b637-dd7475fbae44'	System	03 Sep 2020 17:13:36
User entered 'None (1)'	System	03 Sep 2020 17:13:36

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:30', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4f740ee5-69e3-4cd2-b637-dd7475fbae44'	System	03 Sep 2020 17:13:36
User entered 'No (N)'	System	03 Sep 2020 17:13:36

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:31', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4f740ee5-69e3-4cd2-b637-dd7475fbae44'	System	03 Sep 2020 17:13:36
User entered 'No (N)'	System	03 Sep 2020 17:13:36

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:33', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4f740ee5-69e3-4cd2-b637-dd7475fbae44'	System	03 Sep 2020 17:13:36
User entered 'None (1)'	System	03 Sep 2020 17:13:36

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:34', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4f740ee5-69e3-4cd2-b637-dd7475fbae44' User entered '03 Sep 2020 12:13'	System	03 Sep 2020 17:13:36
	System	03 Sep 2020 17:13:36

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 3'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '298d61d9-1eb5-435c-a815-18432eb54202'	System	04 Sep 2020 19:23:10
User entered 'None (1)'	System	04 Sep 2020 19:23:10

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '298d61d9-1eb5-435c-a815-18432eb54202'	System	04 Sep 2020 19:23:10
User entered 'No (N)'	System	04 Sep 2020 19:23:10

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:04', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '298d61d9-1eb5-435c-a815-18432eb54202'	System	04 Sep 2020 19:23:10
User entered 'No (N)'	System	04 Sep 2020 19:23:10

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:06', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '298d61d9-1eb5-435c-a815-18432eb54202'	System	04 Sep 2020 19:23:10
User entered 'None (1)'	System	04 Sep 2020 19:23:10

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:08', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '298d61d9-1eb5-435c-a815-18432eb54202'	System	04 Sep 2020 19:23:10
User entered '04 Sep 2020 14:23'	System	04 Sep 2020 19:23:10

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 4'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:00:49', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a8060e24-b1b8-4333-9afb-62d32aef2ee7'	System	05 Sep 2020 17:01:08
User entered 'None (1)'	System	05 Sep 2020 17:01:08

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:00:51', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a8060e24-b1b8-4333-9afb-62d32aef2ee7'	System	05 Sep 2020 17:01:08
User entered 'No (N)'	System	05 Sep 2020 17:01:08

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:00:53', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a8060e24-b1b8-4333-9afb-62d32aef2ee7' User entered 'No (N)'	System	05 Sep 2020 17:01:08
	System	05 Sep 2020 17:01:08

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:00:54', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a8060e24-b1b8-4333-9afb-62d32aef2ee7'	System	05 Sep 2020 17:01:08
User entered 'None (1)'	System	05 Sep 2020 17:01:08

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:00:57', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a8060e24-b1b8-4333-9afb-62d32aef2ee7' User entered '05 Sep 2020 12:00'	System	05 Sep 2020 17:01:08
	System	05 Sep 2020 17:01:08

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 5'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:42', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '552840ce-1214-46ab-a5a0-1daf64493087' User entered 'None (1)'	System	06 Sep 2020 18:39:51
	System	06 Sep 2020 18:39:51

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:43', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '552840ce-1214-46ab-a5a0-1daf64493087' User entered 'No (N)'	System	06 Sep 2020 18:39:51
	System	06 Sep 2020 18:39:51

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:44', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '552840ce-1214-46ab-a5a0-1daf64493087' User entered 'No (N)'	System	06 Sep 2020 18:39:51
	System	06 Sep 2020 18:39:51

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:45', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '552840ce-1214-46ab-a5a0-1daf64493087'	System	06 Sep 2020 18:39:51
User entered 'None (1)'	System	06 Sep 2020 18:39:51

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:46', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '552840ce-1214-46ab-a5a0-1daf64493087' User entered '06 Sep 2020 13:39'	System	06 Sep 2020 18:39:51
	System	06 Sep 2020 18:39:51

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 6'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:33:58', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2fdeb4f0-2d74-48c9-aa24-764cc70c61cb'	System	07 Sep 2020 19:34:08
User entered 'None (1)'	System	07 Sep 2020 19:34:08

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:33:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2fdeb4f0-2d74-48c9-aa24-764cc70c61cb' User entered 'No (N)'	System	07 Sep 2020 19:34:08
	System	07 Sep 2020 19:34:08

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2fdeb4f0-2d74-48c9-aa24-764cc70c61cb' User entered 'No (N)'	System	07 Sep 2020 19:34:08
	System	07 Sep 2020 19:34:08

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:02', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2fdeb4f0-2d74-48c9-aa24-764cc70c61cb'	System	07 Sep 2020 19:34:08
User entered 'None (1)'	System	07 Sep 2020 19:34:08

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:06', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '2fdeb4f0-2d74-48c9-aa24-764cc70c61cb' User entered '07 Sep 2020 14:34'	System	07 Sep 2020 19:34:08
	System	07 Sep 2020 19:34:08

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 7'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5cf23583-c613-4a92-88bc-29f6be565b6b'	System	08 Sep 2020 18:28:13
User entered 'None (1)'	System	08 Sep 2020 18:28:13

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5cf23583-c613-4a92-88bc-29f6be565b6b' User entered 'No (N)'	System	08 Sep 2020 18:28:13
	System	08 Sep 2020 18:28:13

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:03', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5cf23583-c613-4a92-88bc-29f6be565b6b' User entered 'No (N)'	System	08 Sep 2020 18:28:13
	System	08 Sep 2020 18:28:13

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:07', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5cf23583-c613-4a92-88bc-29f6be565b6b'	System	08 Sep 2020 18:28:13
User entered 'None (1)'	System	08 Sep 2020 18:28:13

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:09', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '5cf23583-c613-4a92-88bc-29f6be565b6b' User entered '08 Sep 2020 13:28'	System	08 Sep 2020 18:28:13
	System	08 Sep 2020 18:28:13

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:22', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0bd0b0c4-946b-4808-9be6-e25a218769b5' User entered 'None (0)'	System	02 Sep 2020 22:47:46
	System	02 Sep 2020 22:47:46

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:24', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0bd0b0c4-946b-4808-9be6-e25a218769b5' User entered 'None (0)'	System	02 Sep 2020 22:47:46
	System	02 Sep 2020 22:47:46

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:26', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0bd0b0c4-946b-4808-9be6-e25a218769b5' User entered 'None (0)'	System	02 Sep 2020 22:47:46
	System	02 Sep 2020 22:47:46

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:28', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0bd0b0c4-946b-4808-9be6-e25a218769b5' User entered 'None (0)'	System	02 Sep 2020 22:47:46
	System	02 Sep 2020 22:47:46

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:34', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0bd0b0c4-946b-4808-9be6-e25a218769b5'	System	02 Sep 2020 22:47:46
User entered 'None (0)'	System	02 Sep 2020 22:47:46

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:36', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0bd0b0c4-946b-4808-9be6-e25a218769b5'	System	02 Sep 2020 22:47:46
User entered 'None (0)'	System	02 Sep 2020 22:47:46

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:42', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0bd0b0c4-946b-4808-9be6-e25a218769b5' User entered 'No (N)'	System	02 Sep 2020 22:47:46
	System	02 Sep 2020 22:47:46

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-02T17:47:44', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '0bd0b0c4-946b-4808-9be6-e25a218769b5'	System	02 Sep 2020 22:47:46
User entered '02 Sep 2020 17:47'	System	02 Sep 2020 22:47:46

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '02 Sep 2020 17:35'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '02 Sep 2020 20:05'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:15', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a7d931e4-34bd-4bc2-a96b-c32ad34a84a9' User entered 'None (0)'	System	03 Sep 2020 12:01:28
	System	03 Sep 2020 12:01:28

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:16', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a7d931e4-34bd-4bc2-a96b-c32ad34a84a9' User entered 'None (0)'	System	03 Sep 2020 12:01:28
	System	03 Sep 2020 12:01:28

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:18', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a7d931e4-34bd-4bc2-a96b-c32ad34a84a9'	System	03 Sep 2020 12:01:28
User entered 'None (0)'	System	03 Sep 2020 12:01:28

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:20', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a7d931e4-34bd-4bc2-a96b-c32ad34a84a9' User entered 'None (0)'	System	03 Sep 2020 12:01:28
	System	03 Sep 2020 12:01:28

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:21', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a7d931e4-34bd-4bc2-a96b-c32ad34a84a9' User entered 'None (0)'	System	03 Sep 2020 12:01:28
	System	03 Sep 2020 12:01:28

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:22', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a7d931e4-34bd-4bc2-a96b-c32ad34a84a9' User entered 'None (0)'	System	03 Sep 2020 12:01:28
	System	03 Sep 2020 12:01:28

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:24', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a7d931e4-34bd-4bc2-a96b-c32ad34a84a9'	System	03 Sep 2020 12:01:28
User entered 'No (N)'	System	03 Sep 2020 12:01:28

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T07:01:26', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a7d931e4-34bd-4bc2-a96b-c32ad34a84a9' User entered '03 Sep 2020 07:01'	System	03 Sep 2020 12:01:28
	System	03 Sep 2020 12:01:28

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '02 Sep 2020 21:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 2'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:37', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6ce4064b-ba83-47fe-b118-ce50f5791abd' User entered 'None (0)'	System	03 Sep 2020 17:13:50
	System	03 Sep 2020 17:13:50

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:38', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6ce4064b-ba83-47fe-b118-ce50f5791abd' User entered 'None (0)'	System	03 Sep 2020 17:13:50
	System	03 Sep 2020 17:13:50

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:39', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6ce4064b-ba83-47fe-b118-ce50f5791abd' User entered 'None (0)'	System	03 Sep 2020 17:13:50
	System	03 Sep 2020 17:13:50

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:40', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6ce4064b-ba83-47fe-b118-ce50f5791abd' User entered 'None (0)'	System	03 Sep 2020 17:13:50
	System	03 Sep 2020 17:13:50

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:41', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6ce4064b-ba83-47fe-b118-ce50f5791abd' User entered 'None (0)'	System	03 Sep 2020 17:13:50
	System	03 Sep 2020 17:13:50

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:43', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6ce4064b-ba83-47fe-b118-ce50f5791abd' User entered 'None (0)'	System	03 Sep 2020 17:13:50
	System	03 Sep 2020 17:13:50

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:45', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6ce4064b-ba83-47fe-b118-ce50f5791abd' User entered 'No (N)'	System	03 Sep 2020 17:13:50
	System	03 Sep 2020 17:13:50

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-03T12:13:49', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6ce4064b-ba83-47fe-b118-ce50f5791abd' User entered '03 Sep 2020 12:13'	System	03 Sep 2020 17:13:50
	System	03 Sep 2020 17:13:50

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 3'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:10', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6172f85d-ae22-4e9d-9eb6-1cee71de75f3' User entered 'None (0)'	System	04 Sep 2020 19:23:27
	System	04 Sep 2020 19:23:27

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:12', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6172f85d-ae22-4e9d-9eb6-1cee71de75f3' User entered 'None (0)'	System	04 Sep 2020 19:23:27
	System	04 Sep 2020 19:23:27

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:14', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6172f85d-ae22-4e9d-9eb6-1cee71de75f3' User entered 'None (0)'	System	04 Sep 2020 19:23:27
	System	04 Sep 2020 19:23:27

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:16', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6172f85d-ae22-4e9d-9eb6-1cee71de75f3' User entered 'None (0)'	System	04 Sep 2020 19:23:27
	System	04 Sep 2020 19:23:27

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:17', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6172f85d-ae22-4e9d-9eb6-1cee71de75f3' User entered 'None (0)'	System	04 Sep 2020 19:23:27
	System	04 Sep 2020 19:23:27

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:19', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6172f85d-ae22-4e9d-9eb6-1cee71de75f3' User entered 'None (0)'	System	04 Sep 2020 19:23:27
	System	04 Sep 2020 19:23:27

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:21', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6172f85d-ae22-4e9d-9eb6-1cee71de75f3' User entered 'No (N)'	System	04 Sep 2020 19:23:27
	System	04 Sep 2020 19:23:27

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-04T14:23:23', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6172f85d-ae22-4e9d-9eb6-1cee71de75f3' User entered '04 Sep 2020 14:23'	System	04 Sep 2020 19:23:27
	System	04 Sep 2020 19:23:27

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 4'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:00:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3c2b8a2c-49a5-4892-ab39-f8f1ab94a239' User entered 'None (0)'	System	05 Sep 2020 17:01:21
	System	05 Sep 2020 17:01:21

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:01:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3c2b8a2c-49a5-4892-ab39-f8f1ab94a239' User entered 'None (0)'	System	05 Sep 2020 17:01:21
	System	05 Sep 2020 17:01:21

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:01:02', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3c2b8a2c-49a5-4892-ab39-f8f1ab94a239'	System	05 Sep 2020 17:01:21
User entered 'None (0)'	System	05 Sep 2020 17:01:21

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:01:03', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3c2b8a2c-49a5-4892-ab39-f8f1ab94a239' User entered 'None (0)'	System	05 Sep 2020 17:01:21
	System	05 Sep 2020 17:01:21

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:01:05', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3c2b8a2c-49a5-4892-ab39-f8f1ab94a239' User entered 'None (0)'	System	05 Sep 2020 17:01:21
	System	05 Sep 2020 17:01:21

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:01:06', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3c2b8a2c-49a5-4892-ab39-f8f1ab94a239' User entered 'None (0)'	System	05 Sep 2020 17:01:21
	System	05 Sep 2020 17:01:21

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:01:08', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3c2b8a2c-49a5-4892-ab39-f8f1ab94a239' User entered 'No (N)'	System	05 Sep 2020 17:01:21
	System	05 Sep 2020 17:01:21

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-05T12:01:11', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '3c2b8a2c-49a5-4892-ab39-f8f1ab94a239'	System	05 Sep 2020 17:01:21
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 17:01:21

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 5'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:51', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4fb3cfb9-480e-450f-9398-17ccc569d9a0'	System	06 Sep 2020 18:40:01
User entered 'None (0)'	System	06 Sep 2020 18:40:01

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:52', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4fb3cfb9-480e-450f-9398-17ccc569d9a0' User entered 'None (0)'	System	06 Sep 2020 18:40:01
	System	06 Sep 2020 18:40:01

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:53', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4fb3cfb9-480e-450f-9398-17ccc569d9a0' User entered 'None (0)'	System	06 Sep 2020 18:40:01
	System	06 Sep 2020 18:40:01

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:54', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4fb3cfb9-480e-450f-9398-17ccc569d9a0' User entered 'None (0)'	System	06 Sep 2020 18:40:01
	System	06 Sep 2020 18:40:01

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:55', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4fb3cfb9-480e-450f-9398-17ccc569d9a0' User entered 'None (0)'	System	06 Sep 2020 18:40:01
	System	06 Sep 2020 18:40:01

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:57', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4fb3cfb9-480e-450f-9398-17ccc569d9a0' User entered 'None (0)'	System	06 Sep 2020 18:40:01
	System	06 Sep 2020 18:40:01

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:58', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4fb3cfb9-480e-450f-9398-17ccc569d9a0'	System	06 Sep 2020 18:40:01
User entered 'No (N)'	System	06 Sep 2020 18:40:01

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-06T13:39:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4fb3cfb9-480e-450f-9398-17ccc569d9a0' User entered '06 Sep 2020 13:39'	System	06 Sep 2020 18:40:01
	System	06 Sep 2020 18:40:01

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 6'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:09', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1e88feea-c5fd-41b7-b40f-a130bb08ce4e' User entered 'None (0)'	System	07 Sep 2020 19:34:20
	System	07 Sep 2020 19:34:20

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:10', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1e88feea-c5fd-41b7-b40f-a130bb08ce4e' User entered 'None (0)'	System	07 Sep 2020 19:34:20
	System	07 Sep 2020 19:34:20

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:11', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1e88feea-c5fd-41b7-b40f-a130bb08ce4e' User entered 'None (0)'	System	07 Sep 2020 19:34:20
	System	07 Sep 2020 19:34:20

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:12', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1e88feea-c5fd-41b7-b40f-a130bb08ce4e' User entered 'None (0)'	System	07 Sep 2020 19:34:20
	System	07 Sep 2020 19:34:20

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:13', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1e88feea-c5fd-41b7-b40f-a130bb08ce4e' User entered 'None (0)'	System	07 Sep 2020 19:34:20
	System	07 Sep 2020 19:34:20

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:14', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1e88feea-c5fd-41b7-b40f-a130bb08ce4e' User entered 'None (0)'	System	07 Sep 2020 19:34:20
	System	07 Sep 2020 19:34:20

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:15', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1e88feea-c5fd-41b7-b40f-a130bb08ce4e' User entered 'No (N)'	System	07 Sep 2020 19:34:20
	System	07 Sep 2020 19:34:20

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-07T14:34:17', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1e88feea-c5fd-41b7-b40f-a130bb08ce4e' User entered '07 Sep 2020 14:34'	System	07 Sep 2020 19:34:20
	System	07 Sep 2020 19:34:20

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	02 Sep 2020 22:23:17
User entered 'Day 7'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:12', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1d56c2d3-acc5-4941-96fa-d800677ef791' User entered 'None (0)'	System	08 Sep 2020 18:28:22
	System	08 Sep 2020 18:28:22

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:13', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1d56c2d3-acc5-4941-96fa-d800677ef791' User entered 'None (0)'	System	08 Sep 2020 18:28:22
	System	08 Sep 2020 18:28:22

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:14', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1d56c2d3-acc5-4941-96fa-d800677ef791' User entered 'None (0)'	System	08 Sep 2020 18:28:22
	System	08 Sep 2020 18:28:22

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:14', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1d56c2d3-acc5-4941-96fa-d800677ef791' User entered 'None (0)'	System	08 Sep 2020 18:28:22
	System	08 Sep 2020 18:28:22

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:16', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1d56c2d3-acc5-4941-96fa-d800677ef791' User entered 'None (0)'	System	08 Sep 2020 18:28:22
	System	08 Sep 2020 18:28:22

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:17', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1d56c2d3-acc5-4941-96fa-d800677ef791' User entered 'None (0)'	System	08 Sep 2020 18:28:22
	System	08 Sep 2020 18:28:22

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:19', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1d56c2d3-acc5-4941-96fa-d800677ef791' User entered 'No (N)'	System	08 Sep 2020 18:28:22
	System	08 Sep 2020 18:28:22

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-09-08T13:28:21', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1d56c2d3-acc5-4941-96fa-d800677ef791' User entered '08 Sep 2020 13:28'	System	08 Sep 2020 18:28:22
	System	08 Sep 2020 18:28:22

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:23:17

US3062102

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:01:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:23:17

US3062102

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	10 Sep 2020 15:35:38
	(b) (4)	

US3062102

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '10 Sep 2020'	Colton King (b) (4)	10 Sep 2020 15:35:38
	(b) (4)	

US3062102

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	10 Sep 2020 15:35:38
	(b) (4)	

US3062102

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty.	Colton King (b) (4)	10 Sep 2020 15:35:38
	(b) (4)	

US3062102

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	10 Sep 2020 15:36:08

US3062102

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '1'	System	10 Sep 2020 15:36:08

US3062102

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	17 Sep 2020 15:08:40
	(b) (4)	

US3062102

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '16 Sep 2020'	Colton King (b) (4)	17 Sep 2020 15:08:40
	(b) (4)	

US3062102

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	17 Sep 2020 15:08:40
	(b) (4)	

US3062102

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty.	Colton King (b) (4)	17 Sep 2020 15:08:40
	(b) (4)	

US3062102

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	17 Sep 2020 15:06:22
	(b) (4)	

US3062102

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'I'	System	17 Sep 2020 15:06:22

US3062102

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	23 Sep 2020 20:22:56
	(b) (4)	

US3062102

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '23 Sep 2020'	Janna Martinez (b) (4)	23 Sep 2020 20:22:56
	(b) (4)	

US3062102

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	23 Sep 2020 20:22:56
	(b) (4)	

US3062102

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	23 Sep 2020 20:22:56
	(b) (4)	

US3062102

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	Janna Martinez (b) (4) (b) (4)	23 Sep 2020 20:23:00

US3062102

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '1'	System	23 Sep 2020 20:23:00

US3062102

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	30 Sep 2020 21:18:25
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '30 Sep 2020'	(b) (4) Colton King (b) (4)	30 Sep 2020 21:18:25
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[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 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Clinic (Clinic)'	(b) (4) Colton King (b) (4)	30 Sep 2020 21:18:25

US3062102

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'VISIT3'	System	30 Sep 2020 21:18:25

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	30 Sep 2020 21:19:02
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '30 Sep 2020'	(b) (4) Colton King (b) (4)	30 Sep 2020 21:19:02

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '15:06'	Colton King (b) (4)	30 Sep 2020 21:19:02
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '30 Sep 2020 15:06'	System	30 Sep 2020 21:19:02

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '98.0' F	Colton King (b) (4)	30 Sep 2020 21:19:02
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	30 Sep 2020 21:19:02
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty.	Colton King (b) (4)	30 Sep 2020 21:19:02
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '78'	Colton King (b) (4)	30 Sep 2020 21:19:02
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'bpm'	System	30 Sep 2020 21:19:02

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '16'	Colton King (b) (4)	30 Sep 2020 21:19:02
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'breaths/min'	System	30 Sep 2020 21:19:02

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered '136'	(b) (4) Colton King (b) (4) (b) (4)	30 Sep 2020 21:19:02

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'mmHg'	System	30 Sep 2020 21:19:02

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '88'	Colton King (b) (4)	30 Sep 2020 21:19:02
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered 'mmHg'	System	30 Sep 2020 21:19:02

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30

US3062102

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30

US3062102

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	30 Sep 2020 21:19:07
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered empty.	Colton King (b) (4)	30 Sep 2020 21:19:07
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	30 Sep 2020 21:19:16
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '30 Sep 2020'	Colton King (b) (4)	30 Sep 2020 21:19:16
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
	(b) (4)	
User entered '15:25'	Colton King (b) (4)	30 Sep 2020 21:19:16
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '30 Sep 2020 15:25'	System	30 Sep 2020 21:19:16

US3062102

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:25:26
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	12 Oct 2020 23:17:29
	(b) (4)	

US3062102

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '1'	System	12 Oct 2020 23:17:29

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 64'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-10-05T08:00:04', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '84148339-3932-44ec-8e4c-646b72e40b00'	System	05 Oct 2020 13:00:18
User entered 'No (N)'	System	05 Oct 2020 13:00:18

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-10-05T08:00:10', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '84148339-3932-44ec-8e4c-646b72e40b00'	System	05 Oct 2020 13:00:18
User entered 'No (N)'	System	05 Oct 2020 13:00:18

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-10-05T08:00:13', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '84148339-3932-44ec-8e4c-646b72e40b00' User entered '05 Oct 2020 08:00:13'	System	05 Oct 2020 13:00:18
	System	05 Oct 2020 13:00:18

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 71'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-10-12T08:09:22', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1664e859-05eb-403e-9f01-2afb8cca284e' User entered 'No (N)'	System	12 Oct 2020 13:09:31
	System	12 Oct 2020 13:09:31

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-10-12T08:09:26', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1664e859-05eb-403e-9f01-2afb8cca284e'	System	12 Oct 2020 13:09:31
User entered 'No (N)'	System	12 Oct 2020 13:09:31

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-10-12T08:09:28', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1664e859-05eb-403e-9f01-2afb8cca284e' User entered '12 Oct 2020 08:09:28'	System	12 Oct 2020 13:09:31
	System	12 Oct 2020 13:09:31

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 78'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-10-20T12:24:03', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e8975b78-887e-4c2f-a666-4aaf13b45dd1'	System	20 Oct 2020 17:24:10
User entered 'No (N)'	System	20 Oct 2020 17:24:10

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-10-20T12:24:06', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e8975b78-887e-4c2f-a666-4aaf13b45dd1'	System	20 Oct 2020 17:24:10
User entered 'No (N)'	System	20 Oct 2020 17:24:10

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-10-20T12:24:08', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e8975b78-887e-4c2f-a666-4aaf13b45dd1' User entered '20 Oct 2020 12:24:08'	System	20 Oct 2020 17:24:10
	System	20 Oct 2020 17:24:10

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 92'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-04T10:11:16', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '94d626b7-5176-431b-be20-64dcedc7f7f0'	System	04 Nov 2020 16:11:36
User entered 'No (N)'	System	04 Nov 2020 16:11:36

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-04T10:11:29', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '94d626b7-5176-431b-be20-64dcedc7f7f0'	System	04 Nov 2020 16:11:36
User entered 'No (N)'	System	04 Nov 2020 16:11:36

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-04T10:11:32', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '94d626b7-5176-431b-be20-64dcedc7f7f0' User entered '04 Nov 2020 10:11:32'	System	04 Nov 2020 16:11:36
	System	04 Nov 2020 16:11:36

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 99'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-09T03:56:27', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6d51edf0-7428-48a8-8d27-6413711ca73d'	System	09 Nov 2020 09:56:37
User entered 'No (N)'	System	09 Nov 2020 09:56:37

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-09T03:56:30', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6d51edf0-7428-48a8-8d27-6413711ca73d'	System	09 Nov 2020 09:56:37
User entered 'No (N)'	System	09 Nov 2020 09:56:37

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-09T03:56:32', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '6d51edf0-7428-48a8-8d27-6413711ca73d' User entered '09 Nov 2020 03:56:32'	System	09 Nov 2020 09:56:37
	System	09 Nov 2020 09:56:37

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered 'Day 106'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-16T08:25:06', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7c838a1c-05ca-458e-a262-e362a37ad869'	System	16 Nov 2020 14:25:14
User entered 'No (N)'	System	16 Nov 2020 14:25:14

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-16T08:25:08', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7c838a1c-05ca-458e-a262-e362a37ad869'	System	16 Nov 2020 14:25:14
User entered 'No (N)'	System	16 Nov 2020 14:25:14

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-16T08:25:11', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7c838a1c-05ca-458e-a262-e362a37ad869' User entered '16 Nov 2020 08:25:11'	System	16 Nov 2020 14:25:14
	System	16 Nov 2020 14:25:14

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 21:39:48

US3062102

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:56:45
Data entry locked.	System	05 Aug 2020 21:39:48
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 21:39:48

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-20T09:09:56', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '424a7a0f-4f9d-497f-9996-0b0217c7ac87'	System	20 Nov 2020 15:10:07
User entered 'No (N)'	System	20 Nov 2020 15:10:07

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-20T09:09:58', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '424a7a0f-4f9d-497f-9996-0b0217c7ac87'	System	20 Nov 2020 15:10:07
User entered 'No (N)'	System	20 Nov 2020 15:10:07

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-20T09:10:01', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '424a7a0f-4f9d-497f-9996-0b0217c7ac87'	System	20 Nov 2020 15:10:07
User entered '20 Nov 2020 09:10:01'	System	20 Nov 2020 15:10:07

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-27T08:39:33', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a777d19a-2755-486e-bbf0-61f98217ab56'	System	27 Nov 2020 14:39:41
User entered 'No (N)'	System	27 Nov 2020 14:39:41

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Have you been exposed to someone with 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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-27T08:39:36', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a777d19a-2755-486e-bbf0-61f98217ab56'	System	27 Nov 2020 14:39:41
User entered 'No (N)'	System	27 Nov 2020 14:39:41

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-11-27T08:39:38', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'a777d19a-2755-486e-bbf0-61f98217ab56'	System	27 Nov 2020 14:39:41
User entered '27 Nov 2020 08:39:38'	System	27 Nov 2020 14:39:41

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-04T00:01:33', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'c9449404-cb59-418d-b773-55232544602b'	System	04 Dec 2020 06:01:47
User entered 'No (N)'	System	04 Dec 2020 06:01:47

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-04T00:01:35', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'c9449404-cb59-418d-b773-55232544602b'	System	04 Dec 2020 06:01:47
User entered 'No (N)'	System	04 Dec 2020 06:01:47

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-04T00:01:38', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'c9449404-cb59-418d-b773-55232544602b' User entered '04 Dec 2020 00:01:38'	System	04 Dec 2020 06:01:47
	System	04 Dec 2020 06:01:47

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-11T10:42:20', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd8526e50-1c47-4a57-aa5e-2f074905801f' User entered 'No (N)'	System	11 Dec 2020 16:42:29
	System	11 Dec 2020 16:42:29

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-11T10:42:23', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd8526e50-1c47-4a57-aa5e-2f074905801f' User entered 'No (N)'	System	11 Dec 2020 16:42:29
	System	11 Dec 2020 16:42:29

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-11T10:42:25', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd8526e50-1c47-4a57-aa5e-2f074905801f' User entered '11 Dec 2020 10:42:25'	System	11 Dec 2020 16:42:29
	System	11 Dec 2020 16:42:29

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-18T00:07:09', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '04b2fcc5-6b11-42e6-9158-1e3d0fb937f4'	System	18 Dec 2020 06:07:16
User entered 'No (N)'	System	18 Dec 2020 06:07:16

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-18T00:07:11', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '04b2fcc5-6b11-42e6-9158-1e3d0fb937f4'	System	18 Dec 2020 06:07:16
User entered 'No (N)'	System	18 Dec 2020 06:07:16

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-18T00:07:13', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '04b2fcc5-6b11-42e6-9158-1e3d0fb937f4' User entered '18 Dec 2020 00:07:13'	System	18 Dec 2020 06:07:16
	System	18 Dec 2020 06:07:16

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-25T01:00:52', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ae1925d5-493c-4067-b0bf-51115bb4a2f1' User entered 'No (N)'	System	25 Dec 2020 07:00:58
	System	25 Dec 2020 07:00:58

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-25T01:00:53', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ae1925d5-493c-4067-b0bf-51115bb4a2f1' User entered 'No (N)'	System	25 Dec 2020 07:00:58
	System	25 Dec 2020 07:00:58

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2020-12-25T01:00:56', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ae1925d5-493c-4067-b0bf-51115bb4a2f1' User entered '25 Dec 2020 01:00:56'	System	25 Dec 2020 07:00:58
	System	25 Dec 2020 07:00:58

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-01T09:05:32', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '06244784-0ebc-49a9-b24a-850a2395726f' User entered 'No (N)'	System	01 Jan 2021 15:05:40
	System	01 Jan 2021 15:05:40

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Have you been exposed to someone with 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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-01T09:05:35', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '06244784-0ebc-49a9-b24a-850a2395726f' User entered 'No (N)'	System	01 Jan 2021 15:05:40
	System	01 Jan 2021 15:05:40

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-01T09:05:38', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '06244784-0ebc-49a9-b24a-850a2395726f' User entered '01 Jan 2021 09:05:38'	System	01 Jan 2021 15:05:40
	System	01 Jan 2021 15:05:40

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-08T12:10:58', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1a0e38b9-d802-46ac-ba81-9ff1011f9363'	System	08 Jan 2021 18:11:05
User entered 'No (N)'	System	08 Jan 2021 18:11:05

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Have you been exposed to someone with 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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-08T12:10:59', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1a0e38b9-d802-46ac-ba81-9ff1011f9363'	System	08 Jan 2021 18:11:05
User entered 'No (N)'	System	08 Jan 2021 18:11:05

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-08T12:11:02', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '1a0e38b9-d802-46ac-ba81-9ff1011f9363'	System	08 Jan 2021 18:11:05
User entered '08 Jan 2021 12:11:02'	System	08 Jan 2021 18:11:05

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-15T09:57:37', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4b80c39b-741e-4c01-8a6d-49d435e59716'	System	18 Jan 2021 02:08:03
User entered 'No (N)'	System	18 Jan 2021 02:08:03

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-15T09:57:42', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4b80c39b-741e-4c01-8a6d-49d435e59716'	System	18 Jan 2021 02:08:03
User entered 'No (N)'	System	18 Jan 2021 02:08:03

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-15T09:57:44', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '4b80c39b-741e-4c01-8a6d-49d435e59716'	System	18 Jan 2021 02:08:03
User entered '15 Jan 2021 09:57:44'	System	18 Jan 2021 02:08:03

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-22T15:15:40', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '05fc42c2-8ee5-4112-97c0-90d1b4e9c42b' User entered 'No (N)'	System	22 Jan 2021 21:15:45
	System	22 Jan 2021 21:15:45

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-22T15:15:41', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '05fc42c2-8ee5-4112-97c0-90d1b4e9c42b' User entered 'No (N)'	System	22 Jan 2021 21:15:45
	System	22 Jan 2021 21:15:45

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90812F49-F1DE-49E4-91CE-E115BD981444)', Time: '2021-01-22T15:15:43', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '05fc42c2-8ee5-4112-97c0-90d1b4e9c42b' User entered '22 Jan 2021 15:15:43'	System	22 Jan 2021 21:15:45
	System	22 Jan 2021 21:15:45

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-05T01:42:32', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '27d68be5-418b-4991-ae8b-36daa574efc5'	System	05 Feb 2021 07:42:39
User entered 'No (N)'	System	05 Feb 2021 07:42:39

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-05T01:42:24', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '27d68be5-418b-4991-ae8b-36daa574efc5'	System	05 Feb 2021 07:42:39
User entered 'No (N)'	System	05 Feb 2021 07:42:39

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-05T01:42:35', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '27d68be5-418b-4991-ae8b-36daa574efc5'	System	05 Feb 2021 07:42:39
User entered '05 Feb 2021 01:42:35'	System	05 Feb 2021 07:42:39

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-12T07:22:43', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd053c19a-ea13-4d6b-aeb3-f4942973aa36'	System	12 Feb 2021 13:22:51
User entered 'No (N)'	System	12 Feb 2021 13:22:51

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-12T07:22:46', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd053c19a-ea13-4d6b-aeb3-f4942973aa36' User entered 'No (N)'	System	12 Feb 2021 13:22:51
	System	12 Feb 2021 13:22:51

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-12T07:22:49', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd053c19a-ea13-4d6b-aeb3-f4942973aa36'	System	12 Feb 2021 13:22:51
User entered '12 Feb 2021 07:22:49'	System	12 Feb 2021 13:22:51

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-19T02:03:04', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ac685025-2449-44cc-86bc-a49a3d696725'	System	19 Feb 2021 08:03:37
User entered 'No (N)'	System	19 Feb 2021 08:03:37

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-19T02:03:27', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ac685025-2449-44cc-86bc-a49a3d696725'	System	19 Feb 2021 08:03:37
User entered 'No (N)'	System	19 Feb 2021 08:03:37

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-19T02:03:29', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ac685025-2449-44cc-86bc-a49a3d696725' User entered '19 Feb 2021 02:03:29'	System	19 Feb 2021 08:03:37
	System	19 Feb 2021 08:03:37

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:09:27-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered 'Yes (Y)'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:09:31-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered 'No (N)'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:09:34-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered 'Yes (Y)'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '1'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '1'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '1'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '1'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '1'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '1'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:16-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '0'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Please 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:41-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:10:45-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered 'No (N)'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-26T08:11:57-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'eab38638-2d28-43d8-855a-cf4bebbfef65'	System	26 Feb 2021 14:12:11
User entered '26 Feb 2021 14:11:57'	System	26 Feb 2021 14:12:11

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-07T12:00:19-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '150415ee-e8b6-44e5-82df-49eca39f9dd5'	System	07 Mar 2021 18:00:40
User entered 'No (N)'	System	07 Mar 2021 18:00:40

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-07T12:00:22-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '150415ee-e8b6-44e5-82df-49eca39f9dd5'	System	07 Mar 2021 18:00:40
User entered 'No (N)'	System	07 Mar 2021 18:00:40

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-07T12:00:30-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '150415ee-e8b6-44e5-82df-49eca39f9dd5'	System	07 Mar 2021 18:00:40
User entered '07 Mar 2021 12:00:30'	System	07 Mar 2021 18:00:40

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-12T14:28:50-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e420a62f-5205-4783-b27a-0948f1603a04'	System	12 Mar 2021 20:28:58
User entered 'No (N)'	System	12 Mar 2021 20:28:58

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-12T14:28:52-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e420a62f-5205-4783-b27a-0948f1603a04'	System	12 Mar 2021 20:28:58
User entered 'No (N)'	System	12 Mar 2021 20:28:58

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-12T14:28:54-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'e420a62f-5205-4783-b27a-0948f1603a04'	System	12 Mar 2021 20:28:58
User entered '12 Mar 2021 14:28:54'	System	12 Mar 2021 20:28:58

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-19T08:35:34-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '72872673-bb09-46ce-9f83-e78018b7ed4b'	System	19 Mar 2021 13:35:49
User entered 'No (N)'	System	19 Mar 2021 13:35:49

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-19T08:35:36-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '72872673-bb09-46ce-9f83-e78018b7ed4b'	System	19 Mar 2021 13:35:49
User entered 'No (N)'	System	19 Mar 2021 13:35:49

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-19T08:35:38-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '72872673-bb09-46ce-9f83-e78018b7ed4b' User entered '19 Mar 2021 08:35:38'	System	19 Mar 2021 13:35:49
	System	19 Mar 2021 13:35:49

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-26T21:52:13-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f6e4fc56-3081-4c1a-8610-645ad5b7ba98'	System	27 Mar 2021 02:56:55
User entered 'No (N)'	System	27 Mar 2021 02:56:55

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-26T21:52:15-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f6e4fc56-3081-4c1a-8610-645ad5b7ba98'	System	27 Mar 2021 02:56:55
User entered 'No (N)'	System	27 Mar 2021 02:56:55

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-03-26T21:52:17-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f6e4fc56-3081-4c1a-8610-645ad5b7ba98'	System	27 Mar 2021 02:56:55
User entered '26 Mar 2021 21:52:17'	System	27 Mar 2021 02:56:55

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-04T18:43:53-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7110dc9c-cfef-4efd-a2dc-50090aaf5500'	System	04 Apr 2021 23:44:03
User entered 'No (N)'	System	04 Apr 2021 23:44:03

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-04T18:43:56-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7110dc9c-cfef-4efd-a2dc-50090aaf5500'	System	04 Apr 2021 23:44:03
User entered 'No (N)'	System	04 Apr 2021 23:44:03

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-04T18:43:58-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '7110dc9c-cfef-4efd-a2dc-50090aaf5500'	System	04 Apr 2021 23:44:03
User entered '04 Apr 2021 18:43:58'	System	04 Apr 2021 23:44:03

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-09T21:19:56-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ab30ef56-3de3-4879-8adb-b6306e0b464d'	System	10 Apr 2021 02:20:10
User entered 'No (N)'	System	10 Apr 2021 02:20:10

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-09T21:19:57-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ab30ef56-3de3-4879-8adb-b6306e0b464d'	System	10 Apr 2021 02:20:10
User entered 'No (N)'	System	10 Apr 2021 02:20:10

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-09T21:20:00-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'ab30ef56-3de3-4879-8adb-b6306e0b464d'	System	10 Apr 2021 02:20:10
User entered '09 Apr 2021 21:20:00'	System	10 Apr 2021 02:20:10

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-16T13:35:41-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '9ee3a783-4c20-4f76-bcb7-d2c29c8643fe'	System	16 Apr 2021 18:35:51
User entered 'No (N)'	System	16 Apr 2021 18:35:51

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-16T13:35:42-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '9ee3a783-4c20-4f76-bcb7-d2c29c8643fe'	System	16 Apr 2021 18:35:51
User entered 'No (N)'	System	16 Apr 2021 18:35:51

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-16T13:35:44-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: '9ee3a783-4c20-4f76-bcb7-d2c29c8643fe' User entered '16 Apr 2021 13:35:44'	System	16 Apr 2021 18:35:51
	System	16 Apr 2021 18:35:51

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-23T19:36:36-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'b5df56be-dff6-45d4-bd18-7c69c3f873ca'	System	24 Apr 2021 00:36:43
User entered 'No (N)'	System	24 Apr 2021 00:36:43

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-23T19:36:38-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'b5df56be-dff6-45d4-bd18-7c69c3f873ca'	System	24 Apr 2021 00:36:43
User entered 'No (N)'	System	24 Apr 2021 00:36:43

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-23T19:36:41-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'b5df56be-dff6-45d4-bd18-7c69c3f873ca'	System	24 Apr 2021 00:36:43
User entered '23 Apr 2021 19:36:41'	System	24 Apr 2021 00:36:43

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-30T18:42:32-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd5c6badf-6630-43bb-968d-93311ed20249'	System	30 Apr 2021 23:42:38
User entered 'No (N)'	System	30 Apr 2021 23:42:38

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

Have you been exposed to someone with 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 (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-30T18:42:33-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd5c6badf-6630-43bb-968d-93311ed20249'	System	30 Apr 2021 23:42:38
User entered 'No (N)'	System	30 Apr 2021 23:42:38

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-04-30T18:42:35-05:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'd5c6badf-6630-43bb-968d-93311ed20249'	System	30 Apr 2021 23:42:38
User entered '30 Apr 2021 18:42:35'	System	30 Apr 2021 23:42:38

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:50:23

US3062102

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:01:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:23
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:50:23

US3062102

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:01:07

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:55:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-28T12:38:07-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f3eb362d-cf9d-470b-91a9-1c3dcca4d893'	System	01 Mar 2021 19:27:28
User entered 'No (N)'	System	01 Mar 2021 19:27:28

US3062102

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:01:07

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:55:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51C02A9C-E812-4644-B1DA-DC18B7E373A9)', Time: '2021-02-28T12:38:10-06:00', User OID: 'PatientReportedOutcome (US3062102)', ODM File OID: 'f3eb362d-cf9d-470b-91a9-1c3dcca4d893'	System	01 Mar 2021 19:27:28
User entered '28 Feb 2021 12:38:10'	System	01 Mar 2021 19:27:28

US3062102

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:56:51
	(b) (4)	
User entered 'Yes (Y)'	Justin Phillips (b) (4)	27 Oct 2020 16:38:38
	(b) (4)	

US3062102

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:56:51
	(b) (4)	
User entered '27 Oct 2020'	Justin Phillips (b) (4)	27 Oct 2020 16:38:38
	(b) (4)	

US3062102

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:56:51
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Justin Phillips (b) (4)	27 Oct 2020 16:38:38
	(b) (4)	

US3062102

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:56:51
	(b) (4)	
User entered empty.	Justin Phillips (b) (4)	27 Oct 2020 16:38:38
	(b) (4)	

US3062102

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:56:51
	(b) (4)	
User entered 'Yes (Y)'	Justin Phillips (b) (4)	27 Oct 2020 16:38:25
	(b) (4)	

US3062102

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:30
User entered '1'	System	27 Oct 2020 16:38:25

US3062102

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4)	30 Nov 2020 23:52:59

US3062102

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered '30 Nov 2020'	Riley King (b) (4)	30 Nov 2020 23:52:59

US3062102

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	30 Nov 2020 23:52:59
	(b) (4)	

US3062102

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered empty.	Riley King (b) (4)	30 Nov 2020 23:52:59
	(b) (4)	

US3062102

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	Riley King (b) (4)	30 Nov 2020 23:53:03

US3062102

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered 'I'	System	30 Nov 2020 23:53:03

US3062102

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	Riley King (b) (4)	29 Dec 2020 21:11:57

US3062102

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered '29 Dec 2020'	Riley King (b) (4)	29 Dec 2020 21:11:57

US3062102

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	29 Dec 2020 21:11:57

US3062102

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered empty.	(b) (4) Riley King (b) (4)	29 Dec 2020 21:11:57

US3062102

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	Riley King (b) (4)	29 Dec 2020 21:11:49

US3062102

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered 'I'	System	29 Dec 2020 21:11:49

US3062102

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	Riley King (b) (4)	31 Jan 2021 17:05:17

US3062102

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered '27 Jan 2021'	Riley King (b) (4)	31 Jan 2021 17:05:17
	(b) (4)	

US3062102

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	31 Jan 2021 17:05:17

US3062102

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered empty.	(b) (4) Riley King (b) (4)	31 Jan 2021 17:05:17

US3062102

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	31 Jan 2021 17:05:24

US3062102

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered '1'	System	31 Jan 2021 17:05:24

US3062102

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4)	
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:16:28
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	Janna Martinez (b) (4)	30 Mar 2021 21:30:18
User entered 'Yes (Y)'	(b) (4)	
	marissa Mueller (b) (4)	19 Feb 2021 22:39:47
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4)	
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 03:15:34
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' answered with 'DATA CORRECTED' (Site from DM).	Janna Martinez (b) (4)	10 Mar 2021 21:01:16
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4)	
User entered '15 Feb 2021'	(b) (4), (b) (6)	09 Mar 2021 10:03:17
	marissa Mueller (b) (4)	19 Feb 2021 22:39:47
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Clinic (Clinic)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:47
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered 'VISIT4'	System	19 Feb 2021 22:39:47

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:18:10
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered '15 Feb 2021'	marissa Mueller (b) (4)	01 Apr 2021 19:18:10
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered '11:04'	marissa Mueller (b) (4)	01 Apr 2021 19:18:10
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered '15 Feb 2021 11:04'	System	01 Apr 2021 19:18:10

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered '98.7' F	marissa Mueller (b) (4)	01 Apr 2021 19:18:10
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Oral (Oral)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:18:10
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:18:10
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered '92'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:18:10
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered 'bpm'	System	01 Apr 2021 19:18:10

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered '16'	marissa Mueller (b) (4)	01 Apr 2021 19:18:10
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered 'breaths/min'	System	01 Apr 2021 19:18:10

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered '131'	marissa Mueller (b) (4)	01 Apr 2021 19:18:10
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered 'mmHg'	System	01 Apr 2021 19:18:10

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered '75'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:18:10
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered 'mmHg'	System	01 Apr 2021 19:18:10

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28

US3062102

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:54:13
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 05:56:58
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28

US3062102

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:06
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:52:16
User closed query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:54:38
Query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4) (b) (4)	20 Apr 2021 16:17:30
Signature has been broken.	marissa Mueller (b) (4) (b) (4)	20 Apr 2021 16:17:11
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	20 Apr 2021 16:17:11
User opened query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:09:51
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:09:51
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:45

US3062102

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' answered with 'Visit 4- only symptom directed is required OL Day 29- investigator is required to assess lymph nodes and injection arm ie part of a physical. If visit 4 did not require lab but OI D29 did, we would document as such as each tab is visit/protocol derived. ' (Site from DM).	marissa Mueller (b) (4) (b) (4)	02 Apr 2021 13:31:40
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:33:28
User closed query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:33:28
Query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' answered with 'per protocol, px not required at this visit. This would be the same if immunogenicity was drawn at one and not the other per protocol. Correct as entered' (Site from DM).	marissa Mueller (b) (4) (b) (4)	31 Mar 2021 14:59:00
User opened query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:53:13

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:53:13
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'data correct as entered as Physical is not required for visit 4 but is required for OL-D29' (Site from DM).	Janna Martinez (b) (4)	30 Mar 2021 19:02:27
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:13:20
User entered 'No (N)'	marissa Mueller (b) (4)	19 Feb 2021 22:40:01

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:06
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:52:16
Signature has been broken.	(b) (4) marissa Mueller (b) (4)	20 Apr 2021 16:17:11
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	20 Apr 2021 16:17:11
User signature succeeded.	(b) (4) Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered empty.	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:40:01
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Mar 2021 21:00:28

US3062102

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered '15 Feb 2021'	Janna Martinez (b) (4)	10 Mar 2021 21:00:28

US3062102

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered '11:13'	Janna Martinez (b) (4)	10 Mar 2021 21:00:28

US3062102

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered '15 Feb 2021 11:13'	System	10 Mar 2021 21:00:28

US3062102

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:40:17
	(b) (4)	

US3062102

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:24:28
User entered '1'	System	19 Feb 2021 22:40:17

US3062102

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	Riley King (b) (4)	01 Apr 2021 19:58:59

US3062102

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered '1 Apr 2021'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:58:59

US3062102

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	01 Apr 2021 19:58:59

US3062102

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered empty.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:58:59

US3062102

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:59:04

US3062102

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:39
User entered 'I'	System	01 Apr 2021 19:59:04

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:01:07

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '23 Feb 2021'	Sherry Henning (b) (4)	26 Feb 2021 00:53:09

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:01:07

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '13:33'	Sherry Henning (b) (4)	26 Feb 2021 00:53:09

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:01:07

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '23 Feb 2021 13:33'	System	26 Feb 2021 00:53:09

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:01:07

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Safety Call (Safety Call)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:53:09

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:01:07

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	26 Feb 2021 00:53:09
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Day 1 (Day 1)'	Sherry Henning (b) (4)	26 Feb 2021 00:54:15

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '21 Feb 2021'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered missing code ND - Not Done.	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '%'	System	26 Feb 2021 00:54:15

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:33
User entered missing code ND - Not Done.	Sherry Henning (b) (4) (b) (4)	26 Feb 2021 00:54:15

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Mild (Mild)'	Sherry Henning (b) (4)	26 Feb 2021 00:54:15
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:54:15
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:54:15
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:54:15
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:54:15
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:54:15
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:54:15
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:54:15
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:01:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:54:15

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Day 2 (Day 2)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '22 Feb 2021'	Sherry Henning (b) (4)	26 Feb 2021 00:55:57
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered missing code ND - Not Done.	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '%'	System	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered missing code ND - Not Done.	Sherry Henning (b) (4)	26 Feb 2021 00:55:57
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:18:58
DataPoint Verified.	(b) (4)	12 Apr 2021 23:03:12
User closed query 'please verify as None per source' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 23:02:53
Query 'please verify as None per source' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	12 Apr 2021 21:43:50
Signature has been broken.	(b) (4)	12 Apr 2021 21:43:32
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	12 Apr 2021 21:43:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:22:45
DataPoint Verified.	(b) (4)	12 Apr 2021 21:21:31
User opened query 'please verify as None per source' (Site from CRA).	(b) (4)	12 Apr 2021 21:16:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Not Done (Not Done)'	(b) (4)	26 Feb 2021 00:55:57
	Sherry Henning (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Mild (Mild)'	Sherry Henning (b) (4)	26 Feb 2021 00:55:57
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:55:57
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:55:57
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:55:57
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:18:58
DataPoint Verified.	(b) (4)	12 Apr 2021 23:04:26
User closed query 'please verify as None per source' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 23:03:23
Query 'please verify as None per source' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	12 Apr 2021 21:44:14
Signature has been broken.	(b) (4)	12 Apr 2021 21:43:32
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	12 Apr 2021 21:43:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:23:02
DataPoint Verified.	(b) (4)	12 Apr 2021 21:21:31
User opened query 'please verify as None per source' (Site from CRA).	(b) (4)	12 Apr 2021 21:17:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:18:58
DataPoint Verified.	(b) (4)	12 Apr 2021 23:04:26
User closed query 'please verify as None per source' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 23:03:50
Query 'please verify as None per source' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	12 Apr 2021 21:44:42
Signature has been broken.	(b) (4)	12 Apr 2021 21:43:32
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	12 Apr 2021 21:43:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:23:16
DataPoint Verified.	(b) (4)	12 Apr 2021 21:21:31
User opened query 'please verify as None per source' (Site from CRA).	(b) (4)	12 Apr 2021 21:17:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:01:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:18:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:04:26
User closed query 'please verify as None per source' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 23:04:02
Query 'please verify as None per source' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	12 Apr 2021 21:45:01
Signature has been broken.	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	12 Apr 2021 21:43:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 21:23:29
DataPoint Verified.		12 Apr 2021 21:21:31
User opened query 'please verify as None per source' (Site from CRA).		12 Apr 2021 21:17:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:55:57

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Day 3 (Day 3)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:57:04

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User closed query 'Per ETRTR: Since COVID Negative report was available until 28Feb21, please add log lines from 24Feb21 through 28Feb21, thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
Query 'Per ETRTR: Since COVID Negative report was available until 28Feb21, please add log lines from 24Feb21 through 28Feb21, thanks.' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	08 Apr 2021 14:00:54
User opened query 'Per ETRTR: Since COVID Negative report was available until 28Feb21, please add log lines from 24Feb21 through 28Feb21, thanks.' (Site from CRA).	(b) (4)	07 Apr 2021 21:08:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '23 Feb 2021'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:57:04

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	Riley King (b) (4)	08 Apr 2021 15:27:49
	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '95'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '%'	System	08 Apr 2021 15:27:49
User entered empty.	System	08 Apr 2021 14:03:14
User entered '%'	System	26 Feb 2021 00:57:04

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:20:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Riley King (b) (4) (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	marissa Mueller (b) (4) (b) (4)	08 Apr 2021 14:03:14
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4) (b) (4)	08 Apr 2021 14:03:14
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:33
User entered '98.7' F	Sherry Henning (b) (4) (b) (4)	26 Feb 2021 00:57:04

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Mild (Mild)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	marissa Mueller (b) (4) (b) (4)	08 Apr 2021 14:03:14
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4) (b) (4)	08 Apr 2021 14:03:14
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	Sherry Henning (b) (4) (b) (4)	26 Feb 2021 00:57:04

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	marissa Mueller (b) (4) (b) (4)	08 Apr 2021 14:03:14
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4) (b) (4)	08 Apr 2021 14:03:14
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	Sherry Henning (b) (4) (b) (4)	26 Feb 2021 00:57:04

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:03:14
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'None (None)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:04
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:01:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	08 Apr 2021 15:27:49
Signature has been broken.	marissa Mueller (b) (4) (b) (4)	08 Apr 2021 14:03:14
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4) (b) (4)	08 Apr 2021 14:03:14
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:33
User entered 'None (None)'	Sherry Henning (b) (4) (b) (4)	26 Feb 2021 00:57:04

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'Day 4 (Day 4)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '24 Feb 2021'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '0'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '95'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '%'	System	08 Apr 2021 14:04:33

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '98.7' F	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'Mild (Mild)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:01:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:04:33
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'Day 5 (Day 5)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '25 Feb 2021'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '0'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '97'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '%'	System	08 Apr 2021 14:06:09

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '98.2' F	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'Mild (Mild)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) a Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) sa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:01:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'Day 6 (Day 6)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '26 Feb 2021'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '0'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '95'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '%'	System	08 Apr 2021 14:07:18

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '97.8' F	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'Mild (Mild)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)'	marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
	(b) (4)	
User entered 'None (None)'	marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:01:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:07:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'Day 7 (Day 7)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '27 Feb 2021'	(b) (4) marissa Mueller (b) (4) (b) (4)	08 Apr 2021 14:08:24

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '0'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '99'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '%'	System	08 Apr 2021 14:08:24

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '98.0' F	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'Mild (Mild)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:01:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:08:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'Day 8 (Day 8)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '28 Feb 2021'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '0'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '98'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '%'	System	08 Apr 2021 14:09:18

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '98.0' F	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:01:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:09:18
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'Day 9 (Day 9)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '01 Mar 2021'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '0'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '99'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '%'	System	08 Apr 2021 14:11:49

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered '98.0' F	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:01:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:21:31
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:32
User entered 'None (None)'	(b) (4) marissa Mueller (b) (4)	08 Apr 2021 14:11:49
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:01:07

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '24 Feb 2021'	Sherry Henning (b) (4)	26 Feb 2021 00:57:46
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:01:07

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:57:46

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Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:01:07

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	10 Mar 2021 21:04:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 21:04:45
User entered 'No (N)' reason for change: Data Entry Error	Janna Martinez (b) (4)	10 Mar 2021 21:04:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	26 Feb 2021 00:57:46
User entered empty.	Sherry Henning (b) (4)	26 Feb 2021 00:57:46

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Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:01:07

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '24 Feb 2021'	Sherry Henning (b) (4)	26 Feb 2021 00:57:46

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Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:01:07

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:46
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:01:07

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	Sherry Henning (b) (4)	26 Feb 2021 00:57:46

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Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:01:07

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	26 Feb 2021 00:57:46
	(b) (4)	

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Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:01:07

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 00:57:46

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Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:01:07

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	26 Feb 2021 00:57:46
	(b) (4)	

US3062102

Folder: Covid-19 Assessment 23 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:01:07

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:06
User entered '0'	System	10 Mar 2021 21:04:45

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:01:07

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User accepted default value 'Day 3 (Day 3)'	marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:01:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:01:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:01:07

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User accepted default value 'Day 5 (Day 5)'	marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:01:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:01:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:01:07

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User accepted default value 'Day 7 (Day 7)'	marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:01:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:01:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:01:07

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User accepted default value 'Day 9 (Day 9)'	marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:01:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:01:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:01:07

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User accepted default value 'Day 14 (Day 14)'	marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:01:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:01:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:01:07

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User accepted default value 'Day 21 (Day 21)'	marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:01:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:01:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:01:07

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User accepted default value 'Day 28 (Day 28)'	marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:01:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:01:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	10 Mar 2021 22:19:42
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	26 Feb 2021 00:59:53
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '24 Feb 2021'	Sherry Henning (b) (4)	26 Feb 2021 00:59:53
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	26 Feb 2021 00:59:53
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User entered 'SICKD1'	System	26 Feb 2021 00:59:53

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	26 Feb 2021 01:01:13
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '24 Feb 2021'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 01:01:13

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '15:42'	Sherry Henning (b) (4)	26 Feb 2021 01:01:13
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User entered '24 Feb 2021 15:42'	System	26 Feb 2021 01:01:13

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Mar 2021 21:03:44
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Mar 2021 21:03:44
User entered '180.0' cm reason for change: Data Entry Error	Janna Martinez (b) (4)	10 Mar 2021 21:03:44
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Feb 2021 01:01:13
User entered empty.	Sherry Henning (b) (4)	26 Feb 2021 01:01:13
	(b) (4)	
DataPoint set to visible.	System	26 Feb 2021 00:59:53

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Mar 2021 21:03:44
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Mar 2021 21:03:44
User entered '131.0' kg reason for change: Data Entry Error	Janna Martinez (b) (4)	10 Mar 2021 21:03:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Feb 2021 01:01:13
User entered empty.	System	26 Feb 2021 01:01:13
DataPoint set to visible.	Sherry Henning (b) (4)	26 Feb 2021 01:01:13
	(b) (4)	26 Feb 2021 00:59:53
	System	26 Feb 2021 00:59:53

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '98.7' F	Sherry Henning (b) (4)	26 Feb 2021 01:01:13
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	26 Feb 2021 01:01:13
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	Sherry Henning (b) (4)	26 Feb 2021 01:01:13

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '92'	Sherry Henning (b) (4)	26 Feb 2021 01:01:13
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User entered 'bpm'	System	26 Feb 2021 01:01:13

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '14'	Sherry Henning (b) (4)	26 Feb 2021 01:01:13
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User entered 'breaths/min'	System	26 Feb 2021 01:01:13

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '132'	Sherry Henning (b) (4)	26 Feb 2021 01:01:13
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User entered 'mmHg'	System	26 Feb 2021 01:01:13

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '70'	Sherry Henning (b) (4)	26 Feb 2021 01:01:13
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User entered 'mmHg'	System	26 Feb 2021 01:01:13

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38

US3062102

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38

US3062102

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Sherry Henning (b) (4)	26 Feb 2021 01:01:23

US3062102

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '24 Feb 2021'	(b) (4) Sherry Henning (b) (4)	26 Feb 2021 01:01:23

US3062102

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:01:07

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	26 Feb 2021 01:01:35
	(b) (4)	

US3062102

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:01:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '24 Feb 2021'	Sherry Henning (b) (4)	26 Feb 2021 01:01:35
	(b) (4)	

US3062102

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

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Jan 2021 17:34:19

US3062102

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

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '14 Jan 2021'	Janna Martinez (b) (4)	15 Jan 2021 17:34:19

US3062102

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

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	15 Jan 2021 17:34:19

US3062102

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

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 17:34:19

US3062102

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '14 Jan 2021'	Janna Martinez (b) (4)	15 Jan 2021 17:36:01

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:26:12

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Jan 2021 17:36:01

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:26:12

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '14 Jan 2021'	Janna Martinez (b) (4)	15 Jan 2021 17:36:01

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:37:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:36:01
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 01:15:34
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Janna Martinez (b) (4)	15 Jan 2021 17:37:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:36:01
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:15:34
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Janna Martinez (b) (4)	15 Jan 2021 17:37:35
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Janna Martinez (b) (4)	15 Jan 2021 17:36:01
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Janna Martinez (b) (4)	15 Jan 2021 17:37:35
User entered 'No (N)'	Janna Martinez (b) (4)	15 Jan 2021 17:36:01

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '1'	System	15 Jan 2021 17:37:35
User entered empty.	System	15 Jan 2021 17:36:01

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

Form: Unblinding

Generated On: 09 Jun 2021 15:01:07

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '1'	System	15 Jan 2021 17:37:35
User entered empty.	System	15 Jan 2021 17:36:01

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:39:27
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '124.0' kg	Janna Martinez (b) (4)	15 Jan 2021 17:39:27
	(b) (4)	

US3062102

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered empty.	System	15 Jan 2021 17:39:27
DataPoint set to visible.	System	15 Jan 2021 17:37:35

US3062102

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:39:27
	(b) (4)	

US3062102

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '124.0' kg	Janna Martinez (b) (4)	15 Jan 2021 17:39:27
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered empty.	System	15 Jan 2021 17:39:27
DataPoint set to visible.	System	15 Jan 2021 17:37:35

US3062102

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User accepted default value 'Pre-Dose (PREDOSE)'	Janna Martinez (b) (4)	15 Jan 2021 17:39:27
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:39:27
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '14 Jan 2021'	Janna Martinez (b) (4)	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '13:24'	Janna Martinez (b) (4)	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '14 Jan 2021 13:24'	System	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 08:42:09
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	marissa Mueller (b) (4)	21 Jan 2021 21:35:58
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	15 Jan 2021 17:39:27
User entered '96.4' F	Janna Martinez (b) (4)	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '113'	Janna Martinez (b) (4)	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'bpm'	System	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '16'	Janna Martinez (b) (4)	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'breaths/min'	System	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '138'	Janna Martinez (b) (4)	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mmHg'	System	15 Jan 2021 17:39:27

US3062102

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '82'	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:39:27

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mmHg'	System	15 Jan 2021 17:39:27

US3062102

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:39:27
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '124.0' kg	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:39:27
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:01:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered empty.	System	15 Jan 2021 17:39:27
DataPoint set to visible.	System	15 Jan 2021 17:37:35

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User accepted default value 'Post-Dose (POSTDOSE)'	Janna Martinez (b) (4) (b) (4)	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '14 Jan 2021'	Janna Martinez (b) (4)	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '15:07'	Janna Martinez (b) (4)	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '14 Jan 2021 15:07'	System	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '98.4' F	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:40:18
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Oral (Oral)'	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:40:18
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '70'	Janna Martinez (b) (4)	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'bpm'	System	15 Jan 2021 17:40:18

US3062102

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '16'	Janna Martinez (b) (4)	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'breaths/min'	System	15 Jan 2021 17:40:18

US3062102

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '128'	Janna Martinez (b) (4)	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mmHg'	System	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '80'	Janna Martinez (b) (4)	15 Jan 2021 17:40:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mmHg'	System	15 Jan 2021 17:40:18

US3062102

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Jan 2021 17:42:22

US3062102

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '14 Jan 2021'	(b) (4) Martinez (b) (4)	15 Jan 2021 17:42:22
	(b) (4)	

US3062102

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

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Jan 2021 17:42:44

US3062102

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

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:42:44

US3062102

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

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Janna Martinez (b) (4)	15 Jan 2021 17:42:44
	(b) (4)	

US3062102

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

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mRNA-1273'	System	15 Jan 2021 17:42:44
DataPoint set to visible.	System	15 Jan 2021 17:37:35

US3062102

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

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '14 Jan 2021'	Janna Martinez (b) (4)	15 Jan 2021 17:42:44

US3062102

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

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '14:35'	Janna Martinez (b) (4)	15 Jan 2021 17:42:44

US3062102

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

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '14 Jan 2021 14:35'	System	15 Jan 2021 17:42:44

US3062102

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

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Left Arm (LEFT ARM)'	Janna Martinez (b) (4)	15 Jan 2021 17:42:44

US3062102

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

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'ONCE'	System	15 Jan 2021 17:42:44

US3062102

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

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 17:42:44

US3062102

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Jan 2021 17:43:00

US3062102

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '14 Jan 2021'	Janna Martinez (b) (4)	15 Jan 2021 17:43:00

US3062102

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '13:29' reason for change: Data Entry Error	Janna Martinez (b) (4)	15 Jan 2021 17:43:33
	(b) (4)	
User entered '14:35'	Janna Martinez (b) (4)	15 Jan 2021 17:43:00
	(b) (4)	

US3062102

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '14 Jan 2021 13:29'	System	15 Jan 2021 17:43:33
User entered '14 Jan 2021 14:35'	System	15 Jan 2021 17:43:00

US3062102

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Jan 2021 17:43:45

US3062102

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '14 Jan 2021'	Janna Martinez (b) (4)	15 Jan 2021 17:43:45
	(b) (4)	

US3062102

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:01:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '13:28'	Janna Martinez (b) (4)	15 Jan 2021 17:43:45

US3062102

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:01:07

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '14 Jan 2021 13:28'	System	15 Jan 2021 17:43:45

US3062102

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

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	15 Jan 2021 17:44:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 17:44:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Janna Martinez (b) (4)	15 Jan 2021 17:44:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	15 Jan 2021 17:44:11
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:44:11
	(b) (4)	

US3062102

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

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '1'	System	15 Jan 2021 17:44:14
User entered empty.	System	15 Jan 2021 17:44:11

US3062102

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	28 Jan 2021 17:38:57

US3062102

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	22 Feb 2021 07:12:46
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'dev routing' (Site from System).	marissa Mueller (b) (4)	19 Feb 2021 22:37:40
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	16 Feb 2021 20:36:27
User entered '26 Jan 2021'	Janna Martinez (b) (4)	28 Jan 2021 17:38:57
	(b) (4)	

US3062102

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	28 Jan 2021 17:38:57

US3062102

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	28 Jan 2021 17:38:57
	(b) (4)	

US3062102

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	Janna Martinez (b) (4)	28 Jan 2021 17:39:02

US3062102

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '1'	System	28 Jan 2021 17:39:02

US3062102

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '1'	System	28 Jan 2021 17:39:02
DataPoint set to visible.	System	28 Jan 2021 17:39:02

US3062102

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:37:59
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '15 Feb 2021'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:37:59
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Clinic (Clinic)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:37:59
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'OLD29'	System	19 Feb 2021 22:37:59

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User accepted default value 'Pre-Dose (PREDOSE)'	marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '15 Feb 2021'	(b) (4) a Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '11:04'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '15 Feb 2021 11:04'	System	19 Feb 2021 22:39:26

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '98.7' F	marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Oral (Oral)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '92'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'bpm'	System	19 Feb 2021 22:39:26

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '16'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'breaths/min'	System	19 Feb 2021 22:39:26

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '131'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mmHg'	System	19 Feb 2021 22:39:26

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '75'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:01:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mmHg'	System	19 Feb 2021 22:39:26

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User accepted default value 'Post-Dose (POSTDOSE)'	marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '15 Feb 2021'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 22:39:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Feb 2021 22:39:31
User entered '12:32' reason for change: Data Entry Error	marissa Mueller (b) (4)	19 Feb 2021 22:39:31
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 22:39:26
User entered empty.	marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '15 Feb 2021 12:32'	System	19 Feb 2021 22:39:31
User entered empty.	System	19 Feb 2021 22:39:26

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '98.2' F	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Oral (Oral)'	(b) (4) a Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '76'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'bpm'	System	19 Feb 2021 22:39:26

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '12'	(b) (4) a Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'breaths/min'	System	19 Feb 2021 22:39:26

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '136'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mmHg'	System	19 Feb 2021 22:39:26

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '79'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:39:26
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mmHg'	System	19 Feb 2021 22:39:26

US3062102

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:38:17
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Feb 2021 22:38:46
User entered '15 Feb 2021' reason for change: Data Entry Error	marissa Mueller (b) (4)	19 Feb 2021 22:38:46
	(b) (4)	
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Feb 2021 22:38:17
User entered '19 Feb 2021'	marissa Mueller (b) (4)	19 Feb 2021 22:38:17
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:38:40
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:38:40
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

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)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:38:40
	(b) (4)	

US3062102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mRNA-1273'	System	19 Feb 2021 22:38:40
DataPoint set to visible.	System	28 Jan 2021 17:39:02

US3062102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '15 Feb 2021'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:38:40
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '12:00'	marissa Mueller (b) (4)	19 Feb 2021 22:38:40
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '15 Feb 2021 12:00'	System	19 Feb 2021 22:38:40

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:38:40
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'ONCE'	System	19 Feb 2021 22:38:40

US3062102

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:01:07

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 22:38:40

US3062102

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	19 Feb 2021 22:38:24
	(b) (4)	

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '1'	System	19 Feb 2021 22:38:24

US3062102

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	24 Feb 2021 13:23:58

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered '23 Feb 2021'	Riley King (b) (4)	24 Feb 2021 13:23:58

US3062102

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	24 Feb 2021 13:23:58
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:01:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
	(b) (4)	
User entered empty.	Riley King (b) (4)	24 Feb 2021 13:23:58
	(b) (4)	

US3062102

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:45
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	24 Feb 2021 13:23:52

US3062102

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:01:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '1'	System	24 Feb 2021 13:23:52

US3062102

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Mar 2021 21:11:09

US3062102

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Correct as entered, deviation routing ' (Site from System).	(b) (4), (b) (6)	18 Mar 2021 13:14:18
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Correct as entered, deviation routing ' (Site from System).	Riley King (b) (4)	17 Mar 2021 19:11:02
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	10 Mar 2021 21:11:09
User entered '10 Mar 2021'	Janna Martinez (b) (4)	10 Mar 2021 21:11:09
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	10 Mar 2021 21:11:09

US3062102

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:01:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'OLD57'	System	10 Mar 2021 21:11:09

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Mar 2021 21:14:22
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '10 Mar 2021'	Janna Martinez (b) (4)	10 Mar 2021 21:14:22

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '10:17'	Janna Martinez (b) (4)	10 Mar 2021 21:14:22

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '10 Mar 2021 10:17'	System	10 Mar 2021 21:14:22

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '98.8' F	Janna Martinez (b) (4)	10 Mar 2021 21:14:22
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	10 Mar 2021 21:14:22

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	10 Mar 2021 21:14:22
	(b) (4)	

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '95'	Janna Martinez (b) (4)	10 Mar 2021 21:14:22

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'bpm'	System	10 Mar 2021 21:14:22

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '16'	Janna Martinez (b) (4)	10 Mar 2021 21:14:22

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'breaths/min'	System	10 Mar 2021 21:14:22

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '93'	(b) (4) Janna Martinez (b) (4)	10 Mar 2021 21:14:22
	(b) (4)	

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mmHg'	System	10 Mar 2021 21:14:22

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '64'	(b) (4) Janna Martinez (b) (4)	10 Mar 2021 21:14:22
	(b) (4)	

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered 'mmHg'	System	10 Mar 2021 21:14:22

US3062102

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:01:07

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54

US3062102

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	Janna Martinez (b) (4)	10 Mar 2021 21:28:23

US3062102

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:01:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	Janna Martinez (b) (4)	10 Mar 2021 21:28:23

US3062102

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Mar 2021 21:28:38

US3062102

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '10 Mar 2021'	Janna Martinez (b) (4)	10 Mar 2021 21:28:38

US3062102

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '10:27'	Janna Martinez (b) (4)	10 Mar 2021 21:28:38

US3062102

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:01:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:00:54
User entered '10 Mar 2021 10:27'	System	10 Mar 2021 21:28:38

US3062102

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:01:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:56:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:17:20
User entered 'Yes (Y)' reason for change: New Information	Riley King (b) (4) (b) (4)	16 Feb 2021 15:38:37
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	01 Sep 2020 20:10:58

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	16 Feb 2021 15:40:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 15:40:59
Data point term sent to Coder	System	16 Feb 2021 15:39:54
User entered 'Hypertension'	Riley King (b) (4)	16 Feb 2021 15:39:28
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Riley King (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	Riley King (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '8 Feb 2021'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Riley King (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	16 Feb 2021 15:39:28
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:39:28
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:39:28
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	16 Feb 2021 15:39:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:39:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	16 Feb 2021 15:39:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	16 Feb 2021 15:39:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query ' Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:09:35
Query ' Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs.' answered with 'updated per source' (Site from DM).	marissa Mueller (b) (4)	23 Mar 2021 16:47:42
User entered 'None (NONE)' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Mar 2021 16:45:28
User opened query ' Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 08:55:30
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	16 Feb 2021 15:39:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '1'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	16 Feb 2021 15:39:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4)	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 15:39:28

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:58:42
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:27:42
User entered	System	17 Feb 2021 14:26:47
'USA-US090-2021-mRNA-1273-P301000009'		
User entered 'New'	(b) (4), (b) (6)	17 Feb 2021 14:26:47

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:58:44
User coded data point as SOC: Psychiatric disorders, HLT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicidal ideation, LLT: Suicidal ideation - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 15:45:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 15:45:59
	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 15:45:05
User entered 'Suicidal ideation'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:58:47
User entered 'Yes (Y)'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:58:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 15:44:22

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:58:51
User entered 'No (N)'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:58:57
User entered '26 Jan 2021'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:58:55
User entered empty.	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:44:22

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:58:59
User entered 'No (N)'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:01
User entered '3 Feb 2021'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:04
User entered empty.	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:44:22

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:06
User entered 'Grade 4 (Grade 4)'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:16
User entered 'Yes (Y)'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:19
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:21
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:23
User entered '1'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'PV Query: As per the discharge summary, the hospital admission date was 27 Jan 2021. Please confirm If the subject was admitted for unrelated event on 26 Jan 2021. If not, please update hospital admission date in EDC accordingly' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 12:57:40
Query 'PV Query: As per the discharge summary, the hospital admission date was 27 Jan 2021. Please confirm If the subject was admitted for unrelated event on 26 Jan 2021. If not, please update hospital admission date in EDC accordingly' answered with 'reconciled ' (Site from Safety).	Riley King (b) (4) (b) (4)	29 Mar 2021 14:30:14
DataPoint Un-verified.	Riley King (b) (4) (b) (4)	29 Mar 2021 14:29:49
User entered '27 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	29 Mar 2021 14:29:49
User opened query 'PV Query: As per the discharge summary, the hospital admission date was 27 Jan 2021. Please confirm If the subject was admitted for unrelated event on 26 Jan 2021. If not, please update hospital admission date in EDC accordingly' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 22:48:56
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:25
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 15:44:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) [REDACTED]	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6) [REDACTED]	18 Mar 2021 15:59:32
User entered '3 Feb 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 15:44:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:35
User entered 'No (N)'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:37
User entered empty.	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:40
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:42
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:45
User entered '0'	Riley King (b) (4) (b) (4)	16 Feb 2021 15:44:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:48
	(b) (4), (b) (6)	
User closed query 'PV Query: Event relatedness to study drug was reported as not applicable. As subject received study drug , please update relatedness to study drug to related or not related.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 17:13:20
Query 'PV Query: Event relatedness to study drug was reported as not applicable. As subject received study drug , please update relatedness to study drug to related or not related.' answered with 'reconciled.' (Site from Safety).	Riley King (b) (4)	26 Feb 2021 15:22:52
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Riley King (b) (4)	26 Feb 2021 15:22:32
	(b) (4)	
User opened query 'PV Query: Event relatedness to study drug was reported as not applicable. As subject received study drug , please update relatedness to study drug to related or not related.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:57:18
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:51
	(b) (4), (b) (6)	
User closed query 'PV Query: Relatedness to procedure was reported as not applicable. As subject received study drug, please update relatedness to procedure to related or not related.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 17:13:29
Query 'PV Query: Relatedness to procedure was reported as not applicable. As subject received study drug, please update relatedness to procedure to related or not related.' answered with 'reconciled' (Site from Safety).	Riley King (b) (4)	26 Feb 2021 15:23:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Riley King (b) (4)	26 Feb 2021 15:22:32
	(b) (4)	
User opened query 'PV Query: Relatedness to procedure was reported as not applicable. As subject received study drug, please update relatedness to procedure to related or not related.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:57:04
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:59:54
	(b) (4), (b) (6)	
User closed query 'PV Query: Action taken with study drug was reported as not applicable. As subject received treatment dose of mRNA-1273 before the event (14 Jan 2021) and after the event (15 Feb 2021), please update action taken to no change.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 18:47:54
Query 'PV Query: Action taken with study drug was reported as not applicable. As subject received treatment dose of mRNA-1273 before the event (14 Jan 2021) and after the event (15 Feb 2021), please update action taken to no change.' answered with 'reconciled ' (Site from Safety).	Riley King (b) (4)	16 Mar 2021 16:27:13
	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error	Janna Martinez (b) (4)	10 Mar 2021 21:08:21
	(b) (4)	
User opened query 'PV Query: Action taken with study drug was reported as not applicable. As subject received treatment dose of mRNA-1273 before the event (14 Jan 2021) and after the event (15 Feb 2021), please update action taken to no change.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:57:56
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:00:08
User closed query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #23 and 24 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 02:06:04
Query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #23 and 24 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'reconciled' (Site from DM).	Riley King (b) (4) (b) (4)	16 Mar 2021 16:27:53
User entered '0' reason for change: Per Query Resolution	Riley King (b) (4) (b) (4)	16 Mar 2021 16:27:40
User opened query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #23 and 24 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 05:35:39
User entered '1'	Riley King (b) (4) (b) (4)	16 Feb 2021 15:44:22

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:00:14
User entered '1' reason for change: Per Query Resolution	Riley King (b) (4)	16 Mar 2021 16:27:40
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:00:16
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:00:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:00:24
User entered empty.	Riley King (b) (4)	16 Feb 2021 15:44:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:32:38
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so' answered with 'All labs have been faxed ' (Site from Safety).	Riley King (b) (4) (b) (4)	06 Apr 2021 16:56:56
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 11:58:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 12:57:43
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'All lab results have been faxed. ' (Site from Safety).	Riley King (b) (4) (b) (4)	29 Mar 2021 14:30:50
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 22:48:20
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:00:27
User closed query 'PV Query: Please determine if schizophrenia and drug induced paranoia should be reported as a separate adverse event.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 18:49:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 18:49:24
User closed query 'PV Query: PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 18:49:11
User closed query 'PV Query: Please provide which drug caused the drug induced paranoia if available.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 18:49:03
User closed query 'PV Query: Please provide what the subject stated or did that determined that the subject had suicidal thoughts' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 18:48:56
User closed query 'PV Query: Please provide additional event information and determine if unrelated event on 26 Jan 2021 should be reported as an event.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 18:48:45
Query 'PV Query: Please provide additional event information and determine if unrelated event on 26 Jan 2021 should be reported as an event.' answered with 'Faxed' (Site from Safety).	Riley King (b) (4) (b) (4)	16 Mar 2021 20:20:50
Query 'PV Query: PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Faxed' (Site from Safety).	Riley King (b) (4) (b) (4)	16 Mar 2021 20:20:42
Query 'PV Query: PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Faxed' (Site from Safety).	Riley King (b) (4) (b) (4)	16 Mar 2021 20:20:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide what the subject stated or did that determined that the subject had suicidal thoughts' answered with 'Per medical records "patient is appropriate for inpatient admission as he remains delusional and could possibly be a harm to himself ' (Site from Safety).	Riley King (b) (4) (b) (4)	16 Mar 2021 19:46:54
Query 'PV Query: Please provide which drug caused the drug induced paranoia if available.' answered with 'Marijuana added to narrative ' (Site from Safety).	Riley King (b) (4) (b) (4)	16 Mar 2021 16:30:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED SITE DURING OPEN LABEL DAY 29 VISIT OF A RECENT HOSPITALIZATION. THE SUBJECT WAS AT ER FOR AN UNRELATED EVENT ON 1/26/21, AND ENDED UP HAVING A MENTAL CONSULT. IT WAS DETERMINED THE SUBJECT WAS HAVING SUICIDAL THOUGHTS. THE SUBJECT WAS TRASFERED TO THE MENTAL HEALTH FLOOR AT A LOCAL HOSPITAL. ACCORDING TO THE SUBJECT, NO PHARMACOLOGICAL TREATMENT WAS ADMINISTERED, ONLY THERAPY. MEDICAL RECORDS REQUESTED FOR FURTHER INFORMATION. 2/17/2021 RECEIVED MEDICAL RECORDS FROM NMC HEALTH AND SALINA REGIONAL HEALTH CENTER. SUBJECT WAS SEEN IN ER FOR A DIFFERENT AE ON 1/26/2021. THE NEXT DAY 1/27/2021 SUBJECT WAS IN ER FOR SAE SUBJECT WAS DIAGNOSED WITH SCHIZOPHRENIA AND DRUG INDUCED PARANOIA due to marijuana. SUBJECT ATTEMPTED TO GET ADMITTED TO A LOCAL MENTAL HEALTH FACILITY, BUT THERE WERE NO OPEN BEDS. SUBJECT WAS THEN ADMITTED TO SALINA REGIONAL MEDICAL CENTER PSYCHIATRIC FLOOR. SUBJECT WAS PRESCRIBED ZYPREXA 5 MG IN THE MORNING AND 10 MG AT BEDTIME. SUBJECT DID NOT RECEIVE ANY NEW AES AT SALINA REGIONAL MEDICAL CENTER. SUBJECT REPORTS NOT HAVING SUICIDAL THOUGHTS SINCE BEING DISCHARGED FROM THE HOSPITAL.'	Riley King (b) (4) (b) (4)	16 Mar 2021 16:30:15
reason for change: New Information Query 'PV Query: Please determine if schizophrenia and drug induced paranoia should be reported as a separate adverse event.' answered with 'They are already recorded as separate AEs '(Site from Safety).	Riley King (b) (4) (b) (4)	16 Mar 2021 16:29:33
User opened query 'PV Query: Please determine if schizophrenia and drug induced paranoia should be reported as a separate adverse event.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:58:27

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:58:17
User opened query 'PV Query: PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:57:50
User opened query 'PV Query: Please provide which drug caused the drug induced paranoia if available.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:56:34
User opened query 'PV Query: Please provide what the subject stated or did that determined that the subject had suicidal thoughts' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:56:13
User opened query 'PV Query: Please provide additional event information and determine if unrelated event on 26 Jan 2021 should be reported as an event.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:56:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
<p>User entered 'SUBJECT NOTIFIED SITE DURING OPEN LABEL DAY 29 VISIT OF A RECENT HOSPITALIZATION. THE SUBJECT WAS AT ER FOR AN UNRELATED EVENT ON 1/26/21, AND ENDED UP HAVING A MENTAL CONSULT. IT WAS DETERMINED THE SUBJECT WAS HAVING SUICIDAL THOUGHTS. THE SUBJECT WAS TRASFERED TO THE MENTAL HEALTH FLOOR AT A LOCAL HOSPITAL. ACCORDING TO THE SUBJECT, NO PHARMACOLOGICAL TREATMENT WAS ADMINISTERED, ONLY THERAPY. MEDICAL RECORDS REQUESTED FOR FURTHER INFORMATION. 2/17/2021 Received medical records from NMC health and salina regional health center. Subject was seen in ER for a different AE on 1/26/2021. The next day 1/27/2021 subject was in ER for SAE subject was diagnosed with schizophrenia and drug induced paranoia. Subject attempted to get admitted to a local mental health facility, but there were no open beds. Subject was then admitted to salina regional medical center psychiatric floor. Subject was prescribed Zyprexa 5 mg in the morning and 10 mg at bedtime. Subject did not receive any new AEs at salina regional medical center. Subject reports not having suicidal thoughts since being discharged from the hospital.' reason for change: New Information</p>	<p>Riley King (b) (4) (b) (4)</p>	<p>17 Feb 2021 15:02:59</p>
<p>User entered 'Subject notified site during open label day 29 visit of a recent hospitalization. The subject was at ER for an unrelated event on 1/26/21, and ended up having a mental consult. It was determined the subject was having suicidal thoughts. The subject was trasfered to the mental health floor at a local hospital. According to the subject, no pharmacological treatment was administered, only therapy. Medical records requested for further information.'</p>	<p>Riley King (b) (4) (b) (4)</p>	<p>16 Feb 2021 15:44:22</p>

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 15:44:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 15:44:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Feb 2021 15:44:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Peanut allergy - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 21:15:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 21:15:03
	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 15:46:06
User entered 'Allergic reaction to peanut butter'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '26 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
User entered empty.	System	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '26 Jan 2021'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
User entered empty.	System	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'Per CDM: The adverse event started after the first dose, yet "Not applicable" is selected for Relationship to investigational product. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:10:00
Query 'Per CDM: The adverse event started after the first dose, yet "Not applicable" is selected for Relationship to investigational product. Please review and update as appropriate. ' answered with 'updated per source' (Site from DM).	marissa Mueller (b) (4)	23 Mar 2021 16:49:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Mar 2021 16:48:54
User opened query 'Per CDM: The adverse event started after the first dose, yet "Not applicable" is selected for Relationship to investigational product. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 08:56:46
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4) (b) (4)	16 Feb 2021 15:45:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Mar 2021 16:48:54
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:10:16
Query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' answered with 'updated per source' (Site from DM).	marissa Mueller (b) (4) (b) (4)	23 Mar 2021 16:49:27
User entered 'None (NONE)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	23 Mar 2021 16:48:54
User opened query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 08:56:02
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4) (b) (4)	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '1'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	16 Feb 2021 15:45:50
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
User entered '0'	System	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37
User entered '1'	System	16 Feb 2021 15:45:50

US3062102

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:37

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 15:01:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 15:01:00
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 15:00:12
User entered 'Nausea'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '26 Jan 2021'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
User entered empty.	System	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '26 Jan 2021'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
User entered empty.	System	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	[REDACTED]	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4) [REDACTED]	02 Apr 2021 20:30:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User closed query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 15:11:54
Query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	23 Mar 2021 16:50:28
	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error	marissa Mueller (b) (4)	23 Mar 2021 16:50:10
	(b) (4)	
User opened query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 08:57:04
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '1'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:59:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
User entered '0'	System	17 Feb 2021 14:59:56

US3062102

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38
User entered '1'	System	17 Feb 2021 14:59:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:38

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLG: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 15:02:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 15:02:00
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 15:01:14
User entered 'tachycardia'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '26 Jan 2021'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
User entered empty.	System	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '26 Jan 2021'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
User entered empty.	System	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:12:20
Query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4) (b) (4)	23 Mar 2021 16:51:24
User entered 'None (NONE)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	23 Mar 2021 16:51:06
User opened query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 08:57:22
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4) (b) (4)	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '1'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:00:42
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
User entered '0'	System	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50
User entered '1'	System	17 Feb 2021 15:00:42

US3062102

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User coded data point as SOC: Psychiatric disorders, HLT: Schizophrenia NEC, PT: Schizophrenia, LLT: Schizophrenia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 15:02:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 15:02:59
Data point term sent to Coder	System	17 Feb 2021 15:02:15
User entered 'Schizophrenia'	Riley King (b) (4)	17 Feb 2021 15:01:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4)	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '27 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:01:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4)	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 15:01:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	Riley King (b) (4)	17 Feb 2021 15:01:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4)	17 Feb 2021 15:01:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4)	17 Feb 2021 15:01:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 15:01:22

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Folder: Adverse Events

Form: Adverse Events (6)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:01:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Riley King (b) (4)	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:12:36
Query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	24 Mar 2021 12:07:34
User entered 'None (NONE)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	24 Mar 2021 12:07:17
User opened query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit and before the OL-D29 visit. Review and update as appropriate as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 08:57:37
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4) (b) (4)	17 Feb 2021 15:01:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed (CM #25 SAPHRIS) that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	03 Apr 2021 04:23:30
	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed (CM #25 SAPHRIS) that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	01 Apr 2021 19:32:07
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 19:31:41
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed (CM #25 SAPHRIS) that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). User entered '1'	(b) (4), (b) (6)	30 Mar 2021 13:35:21
	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '1' reason for change: Data Entry Error	(b) (4) Riley King (b) (4)	01 Apr 2021 19:31:41
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:01:22

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	17 Feb 2021 15:01:22
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4)	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 15:01:22

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLT: Personality disorders and disturbances in behaviour, HLT: Behaviour and socialisation disturbances, PT: Paranoia, LLT: Paranoia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Feb 2021 15:47:25
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	28 Feb 2021 15:47:25
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 15:02:15
User entered 'Drug induced paranoia'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '27 Jan 2021'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
User entered empty.	System	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '3 Feb 2021'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
User entered empty.	System	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query ' Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit. Review and update as appropriate as per CCGs.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 02:07:45
Query ' Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit. Review and update as appropriate as per CCGs.' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	16 Mar 2021 16:26:04
User entered 'None (NONE)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	16 Mar 2021 16:25:49
User opened query ' Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit. Review and update as appropriate as per CCGs.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 13:07:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4) (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '1'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	17 Feb 2021 15:02:02
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
User entered '0'	System	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59
User entered '1'	System	17 Feb 2021 15:02:02

US3062102

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:59

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 19:18:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 19:18:54
	(b) (4)	
Data point term sent to Coder	System	17 Mar 2021 19:18:21
User entered 'Cough'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '21 Feb 2021'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Sherry Henning (b) (4)	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
User entered empty.	System	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Sherry Henning (b) (4)	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '27 Feb 2021'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
User entered empty.	System	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Sherry Henning (b) (4)	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Sherry Henning (b) (4)	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Sherry Henning (b) (4) (b) (4)	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Sherry Henning (b) (4)	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Sherry Henning (b) (4) (b) (4)	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.	(b) (4)	12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Sherry Henning (b) (4)	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sherry Henning (b) (4)	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'l'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
DataPoint Verified.		12 Apr 2021 20:49:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Mar 2021 19:17:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
User entered '0'	System	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
User entered '1'	System	17 Mar 2021 19:17:59

US3062102

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:01:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:01:07

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User closed query 'please verify use of trazadon (26-27Jan) and vyvanse use per hosp record' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 14:12:06
Query 'please verify use of trazadon (26-27Jan) and vyvanse use per hosp record' answered with 'added' (Site from CRA).	Riley King (b) (4) (b) (4)	18 Mar 2021 21:13:40
User opened query 'please verify use of trazadon (26-27Jan) and vyvanse use per hosp record' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 17:19:01
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:18:25
User entered 'Yes (Y)'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:22:27

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Aug 2020 14:26:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Aug 2020 14:26:47
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 14:26:08
User entered 'Levothyroxine'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Hypothyroidism'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '150'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:18:38
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate.' answered with 'updated' (Site from DM).	Colton King (b) (4)	28 Sep 2020 15:00:35
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Colton King (b) (4)	28 Sep 2020 15:00:28
	(b) (4)	
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:26:08
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication's dosage. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:34:51
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication's dosage. Please correct the unit as appropriate.' answered with 'Updated' (Site from DM).	Justin Phillips (b) (4)	15 Sep 2020 00:29:28
	(b) (4)	
User entered 'IU (IU)' reason for change: Data Entry Error	Justin Phillips (b) (4)	15 Sep 2020 00:29:16
	(b) (4)	
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication's dosage. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 14:57:11
User entered 'mg (mg)'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once daily (QD)'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 07:31:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Colton King (b) (4)	08 Aug 2020 15:01:39
answered with 'Correct per protocol ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 14:26:01
User entered 'un UNK 2008'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Yes (Y)'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4)	08 Aug 2020 14:26:01
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 14:26:01

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 14:26:01

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 14:26:01

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 14:53:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 14:53:46
Data point term sent to Coder	System	08 Aug 2020 14:52:24
User entered 'Effexor'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Depression'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '150'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Colton King (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once daily (QD)'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 07:32:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct per protocol ' (Site from System).	Colton King (b) (4) (b) (4)	08 Aug 2020 15:01:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 14:51:34
User entered 'un UNK 2017'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)' reason for change: Data Entry Error	Janna Martinez (b) (4)	15 Jan 2021 17:44:46
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '14 Dec 2020' reason for change: Data Entry Error	Janna Martinez (b) (4)	15 Jan 2021 17:44:46
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User entered '1'	System	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User entered '1'	System	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:54:54
User entered '804 (804)'	System	08 Aug 2020 14:51:34

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE, PRODUCTSYNONYM: BECLOMETHASONE [BECLOMETASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Aug 2020 23:48:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Aug 2020 23:48:22
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 14:56:27
User entered 'Beclomethasone'	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) [REDACTED]	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6) [REDACTED]	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:56:05

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Asthma'	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '40' reason for change: Data Entry Error	Justin Phillips (b) (4)	15 Sep 2020 00:31:21
	(b) (4)	
User entered '2'	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please provide the actual dose (eg. 40 ug, 80 ug, etc.) for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:35:13
Query 'Per DM CLR: Please provide the actual dose (eg. 40 ug, 80 ug, etc.) for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Justin Phillips (b) (4)	15 Sep 2020 00:31:30
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Justin Phillips (b) (4)	15 Sep 2020 00:31:21
	(b) (4)	
User opened query 'Per DM CLR: Please provide the actual dose (eg. 40 ug, 80 ug, etc.) for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 14:58:33
	(b) (4), (b) (6)	
User entered 'puff (PUFF)'	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once daily (QD)'	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 07:32:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Colton King (b) (4)	08 Aug 2020 15:01:50
answered with 'Correct per protocol ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 14:56:05
User entered 'un UNK 2012'	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Yes (Y)'	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 15:01:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 15:01:55
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	08 Aug 2020 15:01:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 14:56:05
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:56:05
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 14:56:05

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 14:56:05

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 14:56:05

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
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)	08 Aug 2020 14:59:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Aug 2020 14:59:41
	(b) (4)	
Data point term sent to Coder User entered 'Albuterol'	System	08 Aug 2020 14:58:27
	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Asthma'	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '1'	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'puff (PUFF)'	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'as needed (PRN)'	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 07:32:21
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Colton King (b) (4)	08 Aug 2020 15:02:03
answered with 'Correct per protocol ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 14:57:40
User entered 'un UNK 2012'	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Yes (Y)'	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4)	08 Aug 2020 14:57:40
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 14:57:40

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 14:57:40

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 14:57:40

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Aug 2020 15:00:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Aug 2020 15:00:42
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 14:59:28
User entered 'Metformin'	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Please indicate Yes for Diabetes history under D1 Randomization tab' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:29:03
Query 'Please indicate Yes for Diabetes history under D1 Randomization tab' answered with 'please unlock page ' (Site from CRA).	Riley King (b) (4) (b) (4)	12 Apr 2021 21:47:06
User opened query 'Please indicate Yes for Diabetes history under D1 Randomization tab' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:02:38
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Type 2 Diabetes Mellitus'	Colton King (b) (4) (b) (4)	08 Aug 2020 14:59:22

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '500'	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once daily (QD)'	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 07:32:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Colton King (b) (4)	08 Aug 2020 15:02:08
answered with 'Correct per protocol ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 14:59:22
User entered 'un UNK 2012'	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Yes (Y)'	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4)	08 Aug 2020 14:59:22
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 14:59:22

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 14:59:22

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 14:59:22

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 15:02:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 15:02:42
Data point term sent to Coder	System	08 Aug 2020 15:01:29
User entered 'Adderall'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Attention deficit hyperactivity disorder'	Colton King (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '30'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once daily (QD)'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 07:32:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct per protocol ' (Site from System).	Colton King (b) (4) (b) (4)	08 Aug 2020 15:02:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 15:00:53
User entered 'un Jul 2019'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)' reason for change: Data Entry Error	Janna Martinez (b) (4)	15 Jan 2021 17:45:37
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '14 Nov 2020' reason for change: Data Entry Error	Janna Martinez (b) (4)	15 Jan 2021 17:45:37
User entered empty.	(b) (4) Colton King (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Colton King (b) (4) (b) (4)	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User entered '1'	System	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User entered '1'	System	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User entered '804 (804)'	System	08 Aug 2020 15:00:53

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: DEXMETHYLPHENIDATE HYDROCHLORIDE, PRODUCTSYNONYM: FOCALIN [DEXMETHYLPHENIDATE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 17:52:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 17:52:00
	(b) (4)	
Data point term sent to Coder	System	15 Jan 2021 17:50:42
User entered 'FOCALIN'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'ATTENTION DEFICIT HYPERACTIVITY DISORDER'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '30'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once daily (QD)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '15 Nov 2020'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4)	15 Jan 2021 17:45:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4)	08 Aug 2020 15:01:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 17:50:06
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4) (b) (4)	15 Jan 2021 17:45:49
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4) (b) (4)	08 Aug 2020 15:01:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 17:50:06
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4) (b) (4)	15 Jan 2021 17:45:49
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4) (b) (4)	08 Aug 2020 15:01:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 17:50:06
DataPoint activated with code reason code Data required.	Janna Martinez (b) (4) (b) (4)	15 Jan 2021 17:45:49
DataPoint inactivated with code reason code Data not required.	Colton King (b) (4) (b) (4)	08 Aug 2020 15:01:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 17:52:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 17:52:55
	(b) (4)	
Data point term sent to Coder	System	15 Jan 2021 17:51:43
User entered 'EFFEXOR'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'DEPRESSION'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '75'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once daily (QD)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '15 Dec 2020'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Janna Martinez (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 17:50:51

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 17:50:51

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 17:50:51

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
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)	16 Feb 2021 16:29:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 16:29:01
Data point term sent to Coder	System	16 Feb 2021 16:28:03
User entered 'lisinopril'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:04

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:04

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'hypertension'	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '10'	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once daily (QD)'	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '8 Feb 2021'	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Yes (Y)'	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4)	16 Feb 2021 16:27:04
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 16:27:04

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 16:27:04

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 16:27:04

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 16:29:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 16:29:00
Data point term sent to Coder	System	16 Feb 2021 16:28:04
User entered 'influenza vaccine'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'influenza prophylaxis'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0.5'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mL (mL)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Intramuscular (INTRAMUSCULAR)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '28 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '28 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User entered empty.	System	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User entered empty.	System	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:30
User entered empty.	System	16 Feb 2021 16:27:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
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: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:10:58
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:10:58
Data point term sent to Coder	System	16 Feb 2021 16:29:05
User entered 'prednisone'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'allergic reaction to peanut butter'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '24'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User entered empty.	System	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User entered empty.	System	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:09
User entered empty.	System	16 Feb 2021 16:29:02

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
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: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:10:58
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:10:58
Data point term sent to Coder	System	16 Feb 2021 16:30:07
User entered 'prednisone'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'allergic reaction to peanut butter'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '20'	Riley King (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '27 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '27 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User entered empty.	System	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User entered empty.	System	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:01
User entered empty.	System	16 Feb 2021 16:29:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
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: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:10:59
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:10:59
Data point term sent to Coder	System	16 Feb 2021 16:31:07
User entered 'prednisone'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'allergic reaction to peanut butter'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '16'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '28 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '28 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User entered empty.	System	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User entered empty.	System	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:09
User entered empty.	System	16 Feb 2021 16:30:10

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
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: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:10:59
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:10:59
Data point term sent to Coder	System	16 Feb 2021 16:31:08
User entered 'prednisone'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'allergic reaction to peanut butter'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '12'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '29 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '29 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User entered empty.	System	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User entered empty.	System	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:16
User entered empty.	System	16 Feb 2021 16:30:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
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: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:11:00
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:11:00
Data point term sent to Coder	System	16 Feb 2021 16:32:09
User entered 'prednisone'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'allergic reaction to peanut butter'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '8'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Riley King (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '30 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '30 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User entered empty.	System	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User entered empty.	System	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:58:21
User entered empty.	System	16 Feb 2021 16:31:35

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
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: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:11:00
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:11:00
Data point term sent to Coder	System	16 Feb 2021 16:32:09
User entered 'prednisone'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'allergic reaction to peanut butter'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '4'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '31 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '31 Jan 2021'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User entered empty.	System	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User entered empty.	System	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:59:48
User entered empty.	System	16 Feb 2021 16:32:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 07:48:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 07:48:46
Data point term sent to Coder	System	17 Feb 2021 14:53:04
User entered 'Benadryl'	Riley King (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'allergic reaction to peanut butter'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '25'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User entered empty.	System	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User entered empty.	System	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:35
User entered empty.	System	17 Feb 2021 14:52:26

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
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 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:57:08
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:57:08
Data point term sent to Coder	System	17 Feb 2021 14:54:04
User entered 'methylprednisolone'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'allergic reaction to peanut butter'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '125'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User entered empty.	System	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User entered empty.	System	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:03:55
User entered empty.	System	17 Feb 2021 14:53:07

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
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: PROVENTIL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 09:28:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:28:45
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ASTHMA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 02:08:31
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ASTHMA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' answered with 'History of asthma did not worsen ' (Site from DM).	Riley King (b) (4) (b) (4)	16 Mar 2021 20:21:45
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ASTHMA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 11:27:01
Data point term sent to Coder	System	17 Feb 2021 14:54:04

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
User entered 'Proventil(albuterol 2.5mg/0.5mL)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Asthma'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '2.5'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User entered empty.	System	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User entered empty.	System	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:14
User entered empty.	System	17 Feb 2021 14:53:56

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Mar 2021 10:18:36
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Mar 2021 10:18:36
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
Data point term sent to Coder	System	17 Feb 2021 14:56:08
User entered 'Pepcid'	Riley King (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'allergic reaction to peanut butter'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '20'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User entered empty.	System	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User entered empty.	System	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:35
User entered empty.	System	17 Feb 2021 14:55:23

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:57:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:57:05
Data point term sent to Coder	System	17 Feb 2021 14:56:08
User entered 'Zofran'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Nausea'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '4'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User entered empty.	System	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User entered empty.	System	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:49
User entered empty.	System	17 Feb 2021 14:55:52

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:06:55
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:06:55
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 10:28:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 10:28:21
Data point term sent to Coder	System	17 Feb 2021 14:57:09
User entered 'Normal saline'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'allergic reaction to peanut butter'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '1'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Other (OTHER)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'liter'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'other (OTHER)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '1 liter/hour'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User entered empty.	System	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User entered empty.	System	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:56
User entered empty.	System	17 Feb 2021 14:56:44

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE, PRODUCTSYNONYM: ZYPREXA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 14:36:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 14:36:02
	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	29 Mar 2021 14:34:23
	Riley King (b) (4)	29 Mar 2021 14:33:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE, PRODUCTSYNONYM: ZYPREXA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 14:58:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 14:58:59
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 14:58:09
User entered 'Zyprexa'	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) [REDACTED]	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6) [REDACTED]	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:57:31

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Mar 2021 14:33:33
	(b) (4)	
User entered 'schizophrenia' reason for change: Data Entry Error	Riley King (b) (4)	29 Mar 2021 14:33:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
	(b) (4)	
User entered 'Suicidal ideation'	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '5'	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once daily (QD)'	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '28 Jan 2021'	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:27:26
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 'Changed indication to schizophrenia' (Site from DM).	Riley King (b) (4)	29 Mar 2021 14:34:09
	(b) (4)	
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)	29 Mar 2021 11:21:54
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Yes (Y)'	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 14:57:31
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 14:57:31

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 14:57:31

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Feb 2021 14:57:31

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE, PRODUCTSYNONYM: ZYPREXA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 14:36:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 14:36:03
	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	29 Mar 2021 14:35:23
	Riley King (b) (4)	29 Mar 2021 14:34:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE, PRODUCTSYNONYM: ZYPREXA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 14:59:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 14:59:00
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 14:58:11
User entered 'Zyprexa'	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Mar 2021 14:34:58
	(b) (4)	
User entered 'schizophrenia' reason for change: Data Entry Error	Riley King (b) (4)	29 Mar 2021 14:34:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
	(b) (4)	
User entered 'Suicidal ideation'	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '10'	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once daily (QD)'	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Oral (ORAL)'	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 23. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 02:09:44
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 23. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate. ' answered with 'Per medical records this medication is taken once a day every evening. Medication #23 is taken once a day every morning. ' (Site from DM).	Riley King (b) (4) (b) (4)	16 Mar 2021 20:23:22
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 23. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 11:27:37
User entered '28 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:03

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:27:39
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 'changed indication to schizophrenia.' (Site from DM).	Riley King (b) (4)	29 Mar 2021 14:35:22
	(b) (4)	
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)	29 Mar 2021 11:22:07
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4)	17 Feb 2021 14:58:03
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 14:58:03

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 14:58:03

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Feb 2021 14:58:03

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: ASENAPINE MALEATE, PRODUCTSYNONYM: SAPHRIS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:26:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:26:58
Data point term sent to Coder	System	16 Mar 2021 20:26:13
Coding entries removed.	Riley King (b) (4) (b) (4)	16 Mar 2021 20:25:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: ASENAPINE MALEATE, PRODUCTSYNONYM: SAPHRIS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:59:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:59:59
Data point term sent to Coder	System	17 Feb 2021 14:59:11
User entered 'Saphris'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
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)	18 Mar 2021 02:09:57
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 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	16 Mar 2021 20:25:38
User entered 'Schizophrenia' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	16 Mar 2021 20:25:32
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)	07 Mar 2021 11:29:44
User entered 'Anxiety'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '10'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered empty.	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'Other (OTHER)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'sublingual'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '27 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '0'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered '27 Jan 2021'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:16:54
User entered 'No (N)'	Riley King (b) (4) (b) (4)	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User entered empty.	System	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User entered empty.	System	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:06
User entered empty.	System	17 Feb 2021 14:58:54

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	18 Mar 2021 20:59:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Mar 2021 20:59:43
Data point term sent to Coder	System	18 Mar 2021 20:58:39
User entered 'trazadone'	Riley King (b) (4)	18 Mar 2021 20:58:09
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'depression'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '50'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'mg (mg)'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'once daily (QD)'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Oral (ORAL)'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '26 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '27 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
User entered '1'	System	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
User entered '1'	System	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:51
User entered '804 (804)'	System	18 Mar 2021 20:58:09

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: VENLAFAXINE HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Mar 2021 21:14:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Mar 2021 21:14:42
Data point term sent to Coder	System	18 Mar 2021 21:14:15
User entered 'venlafaxine hcl'	Riley King (b) (4)	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'depression'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '75'	Riley King (b) (4)	18 Mar 2021 21:13:29
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'mg (mg)'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	18 Mar 2021 21:13:29
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'once daily (QD)'	Riley King (b) (4)	18 Mar 2021 21:13:29
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	18 Mar 2021 21:13:29
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	18 Mar 2021 21:13:29
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	18 Mar 2021 21:13:29
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '26 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	18 Mar 2021 21:13:29
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '27 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
User entered '1'	System	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
User entered '1'	System	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:59
User entered '804 (804)'	System	18 Mar 2021 21:13:29

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 20:02:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Apr 2021 20:02:07
Data point term sent to Coder	System	01 Apr 2021 20:00:56
User entered 'Trazodone'	Riley King (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	Riley King (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'depression'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '100'	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'mg (mg)'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	01 Apr 2021 19:59:59
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'once daily (QD)'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	01 Apr 2021 19:59:59
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	01 Apr 2021 19:59:59
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '26 Mar 2021'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '0'	Riley King (b) (4)	01 Apr 2021 19:59:59
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	Riley King (b) (4)	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 19:59:59

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 20:03:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 20:03:10
Data point term sent to Coder	System	01 Apr 2021 20:01:58
User entered 'Buspirone'	Riley King (b) (4) (b) (4)	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	01 Apr 2021 20:01:15
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'depression'	(b) (4) Riley King (b) (4)	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '15'	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'mg (mg)'	(b) (4) Riley King (b) (4)	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	01 Apr 2021 20:01:15
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'twice daily (BID)'	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Oral (ORAL)'	Riley King (b) (4)	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	01 Apr 2021 20:01:15
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '26 Mar 2021'	Riley King (b) (4)	01 Apr 2021 20:01:15
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered '0'	Riley King (b) (4)	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4)	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered empty.	Riley King (b) (4)	01 Apr 2021 20:01:15
	(b) (4)	

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
User entered 'No (N)'	Riley King (b) (4)	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:01:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 20:01:15

US3062102

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:01:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Sep 2020 20:11:02
	(b) (4)	

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered	System	17 Feb 2021 14:26:47
'USA-US090-2021-MRNA-1273-P301000009'		

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Richard'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Glover'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '700 Medical Center Dr.'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Newton'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'KS'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '67114'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'US'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 12:58:20
User entered '5'	System	17 Mar 2021 18:51:38
User entered '4'	System	11 Mar 2021 17:16:12
User entered '3'	System	01 Mar 2021 17:14:02
User entered '2'	System	18 Feb 2021 15:12:41
User entered '1'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'USA-US090-2021-MRNA-1273-P301000009'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Richard'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Glover'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '700 Medical Center Dr.'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Newton'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'KS'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '67114'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'US'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 12:58:20
User entered '5'	System	17 Mar 2021 18:51:38
User entered '4'	System	11 Mar 2021 17:16:12
User entered '3'	System	01 Mar 2021 17:14:02
User entered '2'	System	18 Feb 2021 15:12:41
User entered '1'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:01:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
User entered '17/Feb/2021 09:28'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:01:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '1'	(b) (4), (b) (6)	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered	System	17 Feb 2021 14:26:47
'USA-US090-2021-MRNA-1273-P301000009'		

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Richard'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Glover'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '700 Medical Center Dr.'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Newton'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'KS'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '67114'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'US'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 12:58:20
User entered '5'	System	17 Mar 2021 18:51:38
User entered '4'	System	11 Mar 2021 17:16:12
User entered '3'	System	01 Mar 2021 17:14:02
User entered '2'	System	18 Feb 2021 15:12:41
User entered '1'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
User entered '18/Feb/2021 10:12'	System	18 Feb 2021 15:12:41

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:01:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 18:50:51
User entered '1'	(b) (4), (b) (6)	18 Feb 2021 15:12:41

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered	System	17 Feb 2021 14:26:47
'USA-US090-2021-MRNA-1273-P301000009'		

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Richard'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Glover'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '700 Medical Center Dr.'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Newton'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'KS'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '67114'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'US'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 12:58:20
User entered '5'	System	17 Mar 2021 18:51:38
User entered '4'	System	11 Mar 2021 17:16:12
User entered '3'	System	01 Mar 2021 17:14:02
User entered '2'	System	18 Feb 2021 15:12:41
User entered '1'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
User entered '01/Mar/2021 12:14'	System	01 Mar 2021 17:14:02

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:01:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 18:50:51
User entered '1'	(b) (4), (b) (6)	01 Mar 2021 17:14:02

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered	System	17 Feb 2021 14:26:47
'USA-US090-2021-MRNA-1273-P301000009'		

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Richard'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Glover'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '700 Medical Center Dr.'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Newton'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'KS'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '67114'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'US'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 12:58:20
User entered '5'	System	17 Mar 2021 18:51:38
User entered '4'	System	11 Mar 2021 17:16:12
User entered '3'	System	01 Mar 2021 17:14:02
User entered '2'	System	18 Feb 2021 15:12:41
User entered '1'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
User entered '11/Mar/2021 09:16'	System	11 Mar 2021 17:16:12

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:01:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 18:50:51
User entered 'l'	(b) (4), (b) (6)	11 Mar 2021 17:16:12

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered	System	17 Feb 2021 14:26:47
'USA-US090-2021-MRNA-1273-P301000009'		

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Richard'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Glover'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '700 Medical Center Dr.'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Newton'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'KS'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '67114'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'US'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 12:58:20
User entered '5'	System	17 Mar 2021 18:51:38
User entered '4'	System	11 Mar 2021 17:16:12
User entered '3'	System	01 Mar 2021 17:14:02
User entered '2'	System	18 Feb 2021 15:12:41
User entered '1'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:01:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
User entered '17/Mar/2021 14:51'	System	17 Mar 2021 18:51:38

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:01:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:57:54
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
User entered '1'	(b) (4), (b) (6)	17 Mar 2021 18:51:38

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered	System	17 Feb 2021 14:26:47
'USA-US090-2021-MRNA-1273-P301000009'		

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Yes (Y)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'No (N)'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Richard'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Glover'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '700 Medical Center Dr.'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'Newton'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'KS'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered '67114'	System	17 Feb 2021 14:26:47

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:17:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:28:22
User entered 'US'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:01:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Mar 2021 12:58:20
User entered '5'	System	17 Mar 2021 18:51:38
User entered '4'	System	11 Mar 2021 17:16:12
User entered '3'	System	01 Mar 2021 17:14:02
User entered '2'	System	18 Feb 2021 15:12:41
User entered '1'	System	17 Feb 2021 14:28:18

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:01:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '30/Mar/2021 07:58'	System	30 Mar 2021 12:58:20

US3062102

Folder: SAE USA-US090-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:01:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:30:33
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	30 Mar 2021 12:58:20