

US3462101 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:39:54

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US3462101

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:43:54

Generated On: 09 Jun 2021 17:39:54

[Participant ID](#)

US3462101

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

US3462101

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Apr 2021 23:03:28

Generated On: 09 Jun 2021 17:39:54

Condition	GERD
Start date (dd MMM yyyy)	01 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Apr 2021 23:03:28

Generated On: 09 Jun 2021 17:39:54

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Apr 2021 23:03:28

Generated On: 09 Jun 2021 17:39:54

Condition	SUB DERMAL SCLEROSIS IN BOTH FEMURS
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Apr 2021 23:03:28

Generated On: 09 Jun 2021 17:39:54

Condition	BONE SPURS IN BOTH FEMURS
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Apr 2021 23:03:28

Generated On: 09 Jun 2021 17:39:54

Condition	BILATERAL HIP ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Apr 2021 23:03:28

Generated On: 09 Jun 2021 17:39:54

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:10 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 15:10
Height (<i>xxx.x</i>)	175.2 cm
Weight (<i>xxx.x</i>)	95.7 kg
BMI (<i>xxx.x</i>)	31.17768 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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) 13 Feb 2021 01:23:30

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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 True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:23:30

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
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) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

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

What was the participant's randomization number? 102644

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

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) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 15:10
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	17:20 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:20
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

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) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 AUG 2020

What was the treatment time? (00:00-23:59) 16:48 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 16:48

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) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

16:37 (24 HR)

Collection date and time (derived)

10 AUG 2020 16:37

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:39	10 AUG 2020 16:39
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

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 17:39:54

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 17:21

PC Open Date & Time

10 AUG 2020 17:08

PC Close Date & Time

10 AUG 2020 19:38

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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 97.7 °F

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

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

PC Time Stamp	10 AUG 2020 20:34
PC Open Date & Time	10 AUG 2020 20:33
PC Close Date & Time	11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

11 AUG 2020 18:51

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 13:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 20:01

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

14 AUG 2020 12:44

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 17:15

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 16:53

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 17:21

PC Open Date & Time

10 AUG 2020 17:08

PC Close Date & Time

10 AUG 2020 19:38

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 20:34

PC Open Date & Time

10 AUG 2020 20:33

PC Close Date & Time

11 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 18:51

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 13:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 20:01

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:45

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 17:15

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 16:53

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 17:21
PC Open Date & Time	10 AUG 2020 17:08
PC Close Date & Time	10 AUG 2020 19:38

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 20:34
PC Open Date & Time	10 AUG 2020 20:33
PC Close Date & Time	11 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

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 ☒

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 18:52
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2047

EAB) (1725)

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 13:22
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2047

EAB) (1725)

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 20:02
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2047

EAB) (1725)

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 12:46
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

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 ☒

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 17:16
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2047

EAB) (1725)

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 16:54
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3462101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	15:46 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 15:46
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	16:46 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 16:46
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3462101

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

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.

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:15 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 16:15

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

US3462101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

16:05 (24 HR)

Collection date and time (derived)

10 SEP 2020 16:05

US3462101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:07	10 SEP 2020 16:07
Nasopharyngeal Swab 2	No		

US3462101

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 16:42

PC Open Date & Time

10 SEP 2020 16:35

PC Close Date & Time

10 SEP 2020 19:05

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

97.3 °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	10 SEP 2020 20:00
PC Open Date & Time	10 SEP 2020 20:00
PC Close Date & Time	11 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

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

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

12 SEP 2020 16:32

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 20:29

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 23:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 21:47

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 23:12

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 16:43

PC Open Date & Time

10 SEP 2020 16:35

PC Close Date & Time

10 SEP 2020 19:05

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 20:00

PC Open Date & Time

10 SEP 2020 20:00

PC Close Date & Time

11 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:33

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 16:32

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 20:29

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 23:04

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:48

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 23:12

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 16:43
PC Open Date & Time	10 SEP 2020 16:35
PC Close Date & Time	10 SEP 2020 19:05

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 20:01
PC Open Date & Time	10 SEP 2020 20:00
PC Close Date & Time	11 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

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 ☒

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:34
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

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 ☒

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 16:32
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

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 ☒

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:29
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2047

EAB) (1725)

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 23:04
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

101 of 2047

EAB) (1725)

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:48
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

103 of 2047

EAB) (1725)

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

	Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 23:13
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

17 SEP 2020 21:10

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462101

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:54

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	17 SEP 2020 21:10
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3462101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:29

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3462101

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

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.

US3462101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 OCT 2020

Collection time (00:00-23:59)

15:35 (24 HR)

Collection date and time (derived)

07 OCT 2020 15:35

US3462101

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:23:30

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 OCT 2020 23:38:34
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

18 OCT 2020 02:40:05

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 06:51:20

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

07 NOV 2020 00:11:33

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 16:45:44

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 02:57:47
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

02 DEC 2020 03:57:38

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 18:33:46
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 09:14:51

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

23 DEC 2020 00:34:46

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

30 DEC 2020 05:12:39

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 JAN 2021 01:03:52
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

13 JAN 2021 00:01:26

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

20 JAN 2021 12:35:59

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 13:39:58

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 00:23:24

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 07:09:35

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 21:25:10
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 09:40:47

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 11:01:10

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 13:34:49

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 11:02:14

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 00:37:49

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

31 MAR 2021 00:15:50

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

07 APR 2021 23:29:10

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

14 APR 2021 08:32:10

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

21 APR 2021 03:29:44

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

28 APR 2021 01:05:02

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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°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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

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13 MAR 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

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27 MAR 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Date and time of submission

Patient Cloud Open Date & Time	12 OCT 2022 00:01
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Patient Cloud Close Date & Time	16 OCT 2022 23:59
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US3462101

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:39:54

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 21:48:18

US3462101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:15:39

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:10:33

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Apr 2021 01:25:58

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:10:34

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Apr 2021 01:25:58

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:10:34

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 22:10:34

Generated On: 09 Jun 2021 17:39:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:04:43

Generated On: 09 Jun 2021 17:39:54

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3462101

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 22:10:34

Generated On: 09 Jun 2021 17:39:54

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.

US3462101

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 22:10:34

Generated On: 09 Jun 2021 17:39:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	14:45 (24 HR)
Collection date and time (derived)	24 MAR 2021 14:45

US3462101

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:10:34

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 05:04:38

Generated On: 09 Jun 2021 17:39:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462101

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 21:10:25

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462101

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462101

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:39:54

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

US3462101

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:39:54

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3462101

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

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

Visit date (dd MMM yyyy)	12 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3462101

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 13:15:39

Generated On: 09 Jun 2021 17:39:54

Date of updated informed consent (*dd MMM yyyy*) 12 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3462101

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

16:04 (24 HR)

Collection date and time (derived)

12 JAN 2021 16:04

US3462101

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	15:42
Collection Date and Time (derived)	12 JAN 2021 15:42

US3462101

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:43:54

Generated On: 09 Jun 2021 17:39:54

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3462101

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 21:10:24

Generated On: 09 Jun 2021 17:39:54

AEID	USA-US093-2020-MRNA-1273-P30 1000005
Adverse event	TRANSIENT ISCHEMIC ATTACK
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	06:00 (24 HR)
AE start date and time (derived)	25 SEP 2020 06:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 SEP 2020
End time (00:00-23:59)	18:00 (24 HR)
AE End Date and Time (derived)	25 SEP 2020 18:00
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	26 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 21:10:24

Generated On: 09 Jun 2021 17:39:54

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3462101

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 21:10:24

Generated On: 09 Jun 2021 17:39:54

PATIENT IS A 45 YEAR OLD
MALE RANDOMIZED ON
10AUG2020 WITH 2ND DOSE
ADMINISTERED AS PER
ROUTINE ON 10SEP2020.
PATIENT WOKE UP MORNING
OF 25SEP2020 WITH POOR
BALANCE, DIFFICULTY
SPEAKING, AND WAS
STRUGGLING TO WALK.
PATIENT WENT TO
EMERGENCY ROOM FOR
EVALUATION. PATIENT
RECEIVED WORK UP WITH CT
SCAN, MRI, AND
ECHOCARDIOGRAM ON
25SEP2020. ALL SCANS WERE
CONSIDERED
UNREMARKABLE. PATIENT
WAS DIAGNOSED WITH
PRESUMPTIVE TIA AND
ADMITTED FOR OBSERVATION.
PATIENT WAS DISCHARGED
26SEP2020 ON ANTIPLATELET
AND STATIN THERAPY .
PATIENT IS SCHEDULED FOR
FOLLOW-UP EVALUATION
WITH CARDIOLOGIST.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 21:10:24

Generated On: 09 Jun 2021 17:39:54

AEID	
Adverse event	HYPERLIPIDEMIA
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 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 21:10:24

Generated On: 09 Jun 2021 17:39:54

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 SUBJECT WAS DIAGNOSED WITH HYPERLIPIDEMIA AFTER DATE OF CONSENT. TREATED WITH ATORVASTATIN. COM MEDS UPDATED

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication ASPIRIN(EC)

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR TIA

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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 SEP 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"/>

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication ATORVASTATIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
TIA/HYPERLIPIDEMIA

Dose per administration 80

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 (2)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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 SEP 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"/>

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication ANNUAL PROPHYLAXIS

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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)		06 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		06 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication PAIN AROUND VACCINE SITE

Dose per administration 600

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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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) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication LAMICTAL

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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 2002	
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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication LEXAPRO

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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 1992
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"/>

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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 2019	
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"/>

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication PAMELOR

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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 1998
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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication MULTIVITAMINS

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENTATION

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication VITAMIN B-12

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENTATION

Dose per administration 1000

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication OYST-CAL-500)

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENTATION

Dose per administration 1250

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 (11)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENTS

Dose per administration 1000

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication IMMUNIZATION

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Mar 2021 19:06:43

Generated On: 09 Jun 2021 17:39:54

	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)		06 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 SEP 2020	MRI BRAIN WO	Adverse Event	
26 SEP 2020	ECHO 2D COMPLETE DOPPLER	Diagnostic	
25 SEP 2020	CTA HEAD NECK	Diagnostic	
25 SEP 2020	CT HEAD WO	Diagnostic	
26 SEP 2020	ECG	Diagnostic	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:39:54

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:39:54

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 ☐

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

SAEID	USA-US093-2020-MRNA-1273-P301000005
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

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Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

SAEID	USA-US093-2020-MRNA-1273-P301000005
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/OCT/2020 08:10
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

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

SAEID	USA-US093-2020-MRNA-1273-P301000005
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/NOV/2020 09:25
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

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 19:43:55

Generated On: 09 Jun 2021 17:39:54

SAEID	USA-US093-2020-MRNA-1273-P301000005
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/NOV/2020 23:57
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

US3462101 (Prod: Crisor, LLC)

US3462101

Form: Participant Creation

Generated On: 09 Jun 2021 17:39:54

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:26:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'US3462101'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 22:09:27

US3462101

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:09:38
User entered 'Yes (Y)'		11 Aug 2020 00:00:32

US3462101

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:09:40
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 22:09:28

US3462101

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:09:42
User entered 'Clinic (Clinic)'		11 Aug 2020 00:00:32

US3462101

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'SCRN'	System	11 Aug 2020 00:00:32

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:02:05
User closed query 'Please provide source document for demographic.' (Site from CRA).		18 Nov 2020 23:01:02
Query 'Please provide source document for demographic.' answered with 'DOB: (b) (6) 1975.' (Site from CRA).		05 Oct 2020 18:59:03
User opened query 'Please provide source document for demographic.' (Site from CRA).		23 Sep 2020 16:13:14
User entered (b) (6) 1975'		10 Aug 2020 22:09:29
	RWS_ENDPOINT ENDPOINT (b) (4)	

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered '45'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'YEARS'	System	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered '45'	System	11 Aug 2020 00:01:14

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered 'Male (M)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:28:31
User closed query 'Per source, subject ethnicity is noted as "Not Hispanic or Latino". Please clarify. ' (Site from CRA).		02 Dec 2020 21:28:28
Query 'Per source, subject ethnicity is noted as "Not Hispanic or Latino". Please clarify. ' answered with 'Data error entry' (Site from CRA).		20 Nov 2020 00:41:00
DataPoint Un-verified.		20 Nov 2020 00:40:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: Data Entry Error		20 Nov 2020 00:40:28
DataPoint Verified.		18 Nov 2020 23:02:05
User opened query 'Per source, subject ethnicity is noted as "Not Hispanic or Latino". Please clarify. ' (Site from CRA).		18 Nov 2020 23:01:58
User entered 'Not Reported (NOT REPORTED)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered 'l'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:39:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:02:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:07

US3462101

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:54

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:13:28
User entered '10 Aug 2020'		11 Aug 2020 00:01:14

US3462101

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:54

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'Aug 2020'	System	11 Aug 2020 00:01:14

US3462101

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:54

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered '2020'	System	11 Aug 2020 00:01:14

US3462101

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:02:44
User entered 'Amendment 2 (2)'		11 Aug 2020 00:01:14

US3462101

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:54

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:02:44
User entered 'Yes (Y)'		11 Aug 2020 00:01:14

US3462101

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:54

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:02:44
User entered empty.		11 Aug 2020 00:01:14

US3462101

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:02:44
User entered empty.		11 Aug 2020 00:01:14

US3462101

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:02:44
User entered 'No (N)'		11 Aug 2020 00:01:14

US3462101

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:02:44
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 22:09:28

US3462101

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:39:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'I'	System	11 Aug 2020 00:01:26

US3462101

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:39:54

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:37:14
User entered 'Yes (Y)'		11 Aug 2020 00:01:26

US3462101

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:39:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:41:20
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:00:33

US3462101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:06:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:06:32
Data point term sent to Coder	System	19 Oct 2020 22:05:30
User entered 'GERD'	(b) (4), (b) (6)	19 Oct 2020 22:04:32

US3462101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:04:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 22:05:41
User entered '01 Jun 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 22:05:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 22:05:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 22:05:17
User entered '0` Jun 2019' (non-conformant).	(b) (4), (b) (6)	19 Oct 2020 22:05:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 22:05:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 22:05:07
User entered '00 Jun 2019' (non-conformant).	(b) (4), (b) (6)	19 Oct 2020 22:05:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 22:04:32
User entered ' ` 2019' (non-conformant).	(b) (4), (b) (6)	19 Oct 2020 22:04:32

US3462101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0' reason for change: Data Entry Error		19 Oct 2020 22:05:33
User entered '1'		19 Oct 2020 22:04:32

US3462101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'Yes (Y)'		19 Oct 2020 22:04:32

US3462101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	23 Apr 2021 23:03:28
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:24:17
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered empty.		19 Oct 2020 22:04:32

US3462101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		19 Oct 2020 22:04:32

US3462101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'Jun 2019'	System	19 Oct 2020 22:05:41
User entered empty.	System	19 Oct 2020 22:04:32

US3462101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered '2019'	System	19 Oct 2020 22:05:41
User entered empty.	System	19 Oct 2020 22:04:32

US3462101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	19 Oct 2020 22:04:32

US3462101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:39:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	19 Oct 2020 22:04:32

US3462101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
DataPoint Verified.		07 Apr 2021 22:59:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate(i.e.: Bipolar Disorders instead of Bipolar). Please reconcile with the Con Med eCRF as necessary.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 05:43:27
' (Site from DM).		
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Jan 2021 22:39:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Jan 2021 22:39:11
Data point term sent to Coder	System	18 Jan 2021 22:39:00
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate(i.e.: Bipolar Disorders instead of Bipolar). Please reconcile with the Con Med eCRF as necessary.	(b) (4), (b) (6)	18 Jan 2021 22:38:43
' answered with 'corrected' (Site from DM).		
DataPoint Un-verified.		18 Jan 2021 22:38:18
Coding entries removed.		18 Jan 2021 22:38:18
User entered 'BIPOLAR Disorder' reason for change: Data Entry Error		18 Jan 2021 22:38:18
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate(i.e.: Bipolar Disorders instead of Bipolar). Please reconcile with the Con Med eCRF as necessary.		12 Jan 2021 02:18:22
' (Site from DM).		
DataPoint Verified.		18 Nov 2020 23:04:12

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:43:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Oct 2020 23:43:48
Data point term sent to Coder	System	21 Oct 2020 23:42:15
User entered 'Bipolar'	(b) (4), (b) (6)	21 Oct 2020 23:41:39

US3462101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'un UNK 1992'		21 Oct 2020 23:41:39

US3462101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		21 Oct 2020 23:41:39

US3462101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'Yes (Y)'		21 Oct 2020 23:41:39

US3462101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered empty.		21 Oct 2020 23:41:39

US3462101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		21 Oct 2020 23:41:39

US3462101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'Jan 1992'	System	21 Oct 2020 23:41:39

US3462101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered '1992'	System	21 Oct 2020 23:41:39

US3462101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	21 Oct 2020 23:41:39

US3462101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:39:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	21 Oct 2020 23:41:39

US3462101

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Connective tissue disorders (excl congenital), HLT: Connective tissue disorders NEC, PT: Scleroderma, LLT: Dermatosclerosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:38:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:38:27
Data point term sent to Coder	System	21 Oct 2020 23:45:19
User entered 'Sub dermal Sclerosis in both femurs'	(b) (4), (b) (6)	21 Oct 2020 23:44:31

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'un UNK 2016'		21 Oct 2020 23:44:31

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		21 Oct 2020 23:44:31

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'Yes (Y)'		21 Oct 2020 23:44:31

US3462101

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered empty.		21 Oct 2020 23:44:31

US3462101

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		21 Oct 2020 23:44:31

US3462101

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'Jan 2016'	System	21 Oct 2020 23:44:31

US3462101

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered '2016'	System	21 Oct 2020 23:44:31

US3462101

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	21 Oct 2020 23:44:31

US3462101

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:39:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	21 Oct 2020 23:44:31

US3462101

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Exostosis, LLT: Bone spur - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:36:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:36:32
Data point term sent to Coder	System	21 Oct 2020 23:47:20
User entered 'Bone Spurs in both Femurs'	(b) (4), (b) (6)	21 Oct 2020 23:46:42

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (v) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'un UNK 2016'		21 Oct 2020 23:46:42

US3462101

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		21 Oct 2020 23:46:42

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'Yes (Y)'		21 Oct 2020 23:46:42

US3462101

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered empty.		21 Oct 2020 23:46:42

US3462101

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		21 Oct 2020 23:46:42

US3462101

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'Jan 2016'	System	21 Oct 2020 23:46:42

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered '2016'	System	21 Oct 2020 23:46:42

US3462101

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	21 Oct 2020 23:46:42

US3462101

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:39:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	21 Oct 2020 23:46:42

US3462101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:04:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Coxarthrosis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:49:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:49:43
Data point term sent to Coder	System	21 Oct 2020 23:48:20
User entered 'Bilateral Hip arthritis'	(b) (4), (b) (6)	21 Oct 2020 23:47:55

US3462101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'un UNK 2016'		21 Oct 2020 23:47:55

US3462101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		21 Oct 2020 23:47:55

US3462101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'Yes (Y)'		21 Oct 2020 23:47:55

US3462101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered empty.		21 Oct 2020 23:47:55

US3462101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		21 Oct 2020 23:47:55

US3462101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'Jan 2016'	System	21 Oct 2020 23:47:55

US3462101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered '2016'	System	21 Oct 2020 23:47:55

US3462101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	21 Oct 2020 23:47:55

US3462101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:39:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	21 Oct 2020 23:47:55

US3462101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:04:12
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 20:15:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 20:15:48
Data point term sent to Coder	System	02 Nov 2020 23:13:56
User entered 'ANXIETY'	(b) (4), (b) (6)	02 Nov 2020 23:12:57

US3462101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'UN UNK 1992'		02 Nov 2020 23:12:57

US3462101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		02 Nov 2020 23:12:57

US3462101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered 'Yes (Y)'		02 Nov 2020 23:12:57

US3462101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered empty.		02 Nov 2020 23:12:57

US3462101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:04:12
User entered '0'		02 Nov 2020 23:12:57

US3462101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'Jan 1992'	System	02 Nov 2020 23:12:57

US3462101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered '1992'	System	02 Nov 2020 23:12:57

US3462101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	02 Nov 2020 23:12:57

US3462101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:39:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered empty.	System	02 Nov 2020 23:12:57

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:22
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:26
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:28
User entered '15:10'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered '10 Aug 2020 15:10'	System	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:44
User entered '175.2' cm	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09
DataPoint set to visible.	System	11 Aug 2020 00:01:26

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:52
User entered '95.7' kg	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09
DataPoint set to visible.	System	11 Aug 2020 00:01:26

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
Amendment Manager: User entered '31.17768'	System	16 Sep 2020 23:50:56
User entered '31.2'	System	13 Aug 2020 17:10:09
DataPoint set to visible.	System	11 Aug 2020 00:01:26

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'kg/m2'	System	13 Aug 2020 17:10:09
DataPoint set to visible.	System	11 Aug 2020 00:01:26

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:06:42
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' (Site from DM).		08 Oct 2020 06:02:04
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:27
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:43:50
DataPoint Verified.		23 Sep 2020 16:48:57
User entered '97.2' F	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 23:06:42
User closed query 'This route does not match what is in source document. Please verify and update accordingly.' (Site from CRA).		18 Nov 2020 23:06:34
User closed query 'Per CDM re-query: Thank you for recording Temperature as Not Done, please remove entry for 'Route of Measurement' as it is not required. (Site from DM).		29 Oct 2020 03:57:47
Query 'Per CDM re-query: Thank you for recording Temperature as Not Done, please remove entry for 'Route of Measurement' as it is not required.' answered with 'Data corrected as advised' (Site from DM).		13 Oct 2020 19:19:53
User entered empty; reason for change Data Entry Error		13 Oct 2020 19:19:17
User opened query 'Per CDM re-query: Thank you for recording Temperature as Not Done, please remove entry for 'Route of Measurement' as it is not required.' (Site from DM).		09 Oct 2020 09:07:51
User closed query 'CDM query: If Temperature is Not Done, then the route of measurement can be left blank. Please verify and confirm if the data can be removed or clarify. Also remove the data from the "If other, specify" datapoint below.' (Site from DM).		09 Oct 2020 09:07:51
Query 'CDM query: If Temperature is Not Done, then the route of measurement can be left blank. Please verify and confirm if the data can be removed or clarify. Also remove the data from the "If other, specify" datapoint below.' answered with 'Screening day and D1 done at the same time. Tympanic temperature recorded' (Site from DM).		08 Oct 2020 15:27:09
User opened query 'CDM query: If Temperature is Not Done, then the route of measurement can be left blank. Please verify and confirm if the data can be removed or clarify. Also remove the data from the "If other, specify" datapoint below.' (Site from DM).		08 Oct 2020 12:30:24

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Route of measurement](#)

Audit	User	Time (GMT)
Query 'This route does not match what is in source document. Please verify and update accordingly.' answered with 'Tympanic route was used' (Site from CRA).	(b) (4), (b) (6)	05 Oct 2020 19:02:44
User entered 'Other (Other)' reason for change: Data Entry Error		05 Oct 2020 19:02:20
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
User opened query 'This route does not match what is in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:50:03
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 23:06:42
User entered empty; reason for change Data Entry Error		13 Oct 2020 19:19:17
DataPoint Un-verified.		05 Oct 2020 19:02:20
User entered 'Tympanic' reason for change: Data Entry Error		05 Oct 2020 19:02:20
DataPoint Verified.		23 Sep 2020 16:50:17
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:06:42
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:50:21
User entered '84'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'bpm'	System	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:06:42
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:50:31
User entered '12'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'breaths/min'	System	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:06:42
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:50:34
User entered '131'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'mmHg'	System	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:06:42
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:04:18
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:50:36
User entered '84'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:09

US3462101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User entered 'mmHg'	System	13 Aug 2020 17:10:09

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58

US3462101

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:53:10
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:20

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:53:13
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).		13 Sep 2020 16:57:29
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 22:49:38
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:20

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:53:52
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:53:55
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

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Folder: Screening

Form: Risk of Exposure

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:54:03
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

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)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:54:26
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:54:29
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

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Folder: Screening

Form: Risk of Exposure

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[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)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:21
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

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Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:26
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

[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)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:27
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

[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)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:30
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

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)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:32
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:35
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:37
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:47
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
User entered 'I'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:50
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

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)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:52
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

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)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:54
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

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)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:56:07
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:56:10
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:39:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:56:12
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:32

US3462101

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:57:09
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:57

US3462101

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:57:11
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:57

US3462101

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[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 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:57:13
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:57

US3462101

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'VISIT1'	System	13 Aug 2020 17:12:57

US3462101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:57:24
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 23:14:16

US3462101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:54

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:58:48
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:27:12
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:27:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 23:14:16
User entered '102644' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 23:14:16

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:54

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:58:51
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 23:14:16

US3462101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:54

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:59:24
User entered 'No (N)'		11 Aug 2020 00:01:54

US3462101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:54

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:59:30
User entered 'No (N)'		11 Aug 2020 00:01:54

US3462101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:54

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:59:45
User entered 'No (N)'		11 Aug 2020 00:01:54

US3462101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:54

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:00:02
User entered 'No (N)'		11 Aug 2020 00:01:54

US3462101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:00:39
User entered 'No (N)'		11 Aug 2020 00:01:54

US3462101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:39:54

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:07:42
User entered 'No (N)'		09 Oct 2020 19:45:06
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:07
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:23:49

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		08 Oct 2020 12:28:21
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:25
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:43:21
DataPoint Verified.		23 Sep 2020 17:08:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 17:12:11
User entered '175.2' cm reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 17:10:45
User entered '175.' (non-conformant).	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:08:42
User entered '95.7' kg reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		08 Oct 2020 12:28:21
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:25
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:43:21
DataPoint Verified.		23 Sep 2020 17:08:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 17:12:11
User entered '175.2' cm reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 17:10:45
User entered '175.' (non-conformant).	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:08:42
User entered '95.7' kg reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:09:39
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 17:12:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 17:12:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 17:10:45
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:09:42
User entered '10 Aug 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
User closed query 'This time does not match with what is in source document. Please verify and update accordingly.' (Site from CRA).		18 Nov 2020 23:08:39
Query 'This time does not match with what is in source document. Please verify and update accordingly.' answered with 'pre dose time is correct' (Site from CRA).		05 Oct 2020 19:14:30
User opened query 'This time does not match with what is in source document. Please verify and update accordingly.' (Site from CRA).		23 Sep 2020 17:15:39
User entered '15:10' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered '10 Aug 2020 15:10'	System	13 Aug 2020 17:12:11
User entered empty.	System	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
User closed query 'Temp does not match with source document. Please verify and update accordingly. ' (Site from CRA).		18 Nov 2020 23:08:47
Query 'Temp does not match with source document. Please verify and update accordingly. ' answered with 'temperature matches' (Site from CRA).		05 Oct 2020 19:15:04
User opened query 'Temp does not match with source document. Please verify and update accordingly. ' (Site from CRA).		23 Sep 2020 17:19:47
User entered '97.2' F reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
User closed query 'Route does not match with source document. Please verify and update accordingly.' (Site from CRA).		18 Nov 2020 23:08:53
Query 'Route does not match with source document. Please verify and update accordingly.' answered with 'route recorded as tympanic' (Site from CRA).		05 Oct 2020 19:15:36
User entered 'Other (Other)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User opened query 'Route does not match with source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 17:23:55
Query 'Temp does not match with source document. Please verify and update accordingly.' canceled (Site from CRA).		23 Sep 2020 17:23:20
User opened query 'Temp does not match with source document. Please verify and update accordingly.' (Site from CRA).		23 Sep 2020 17:21:04
User entered 'Oral (Oral)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User entered 'Tympanic' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:21:09
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).		18 Nov 2020 23:09:10
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'data matches SOP' (Site from CRA).		05 Oct 2020 19:16:00
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).		23 Sep 2020 17:23:14
User entered '84' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'bpm'	System	13 Aug 2020 17:12:11
User entered empty.	System	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:26:03
Query 'This does not match with source document. Please verify and update accordingly.' canceled (Site from CRA).		23 Sep 2020 17:25:08
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).		23 Sep 2020 17:25:05
User entered '12' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'breaths/min'	System	13 Aug 2020 17:12:11
User entered empty.	System	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).		18 Nov 2020 23:09:19
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Data matches SOP' (Site from CRA).		05 Oct 2020 19:16:18
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).		23 Sep 2020 17:26:15
User entered '131' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'mmHg'	System	13 Aug 2020 17:12:11
User entered empty.	System	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
User closed query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).		18 Nov 2020 23:09:21
Query 'This does not match with source document. Please verify and update accordingly.' answered with 'Data matches SOP' (Site from CRA).		05 Oct 2020 19:16:36
User opened query 'This does not match with source document. Please verify and update accordingly.' (Site from CRA).		23 Sep 2020 17:26:34
User entered '84' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'mmHg'	System	13 Aug 2020 17:12:11
User entered empty.	System	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		08 Oct 2020 12:28:21
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:25
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:43:21
DataPoint Verified.		23 Sep 2020 17:08:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 17:12:11
User entered '175.2' cm reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 17:10:45
User entered '175.' (non-conformant).	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:39:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:08:42
User entered '95.7' kg reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:11
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:10:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:27:40
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:27:42
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:28:05
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).		18 Aug 2020 10:56:24
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).		13 Aug 2020 17:12:45
User entered '17:20'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered '10 Aug 2020 17:20'	System	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:28:12
User entered '97.7' F	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
User closed query 'This route is not in source document. Please verify and update accordingly.' (Site from CRA).		18 Nov 2020 23:09:51
Query 'This route is not in source document. Please verify and update accordingly.' answered with 'tympanic route was used' (Site from CRA).		05 Oct 2020 19:18:31
User entered 'Other (Other)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User opened query 'This route is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 17:29:03
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:10:05
DataPoint Un-verified.	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
User entered 'Tympanic' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:03:19
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:29:17
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:29:20
User entered '83'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'bpm'	System	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:29:23
User entered '12'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'breaths/min'	System	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:29:26
User entered '142'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'mmHg'	System	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:29:27
User entered '83'	Danuel Hamlin (b) (4)	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'mmHg'	System	13 Aug 2020 17:12:45

US3462101

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:31:06
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:06

US3462101

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:31:08
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:06

US3462101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	23 Sep 2020 17:32:38
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	11 Aug 2020 00:12:20
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	11 Aug 2020 00:12:20
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	11 Aug 2020 00:03:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 00:03:12

US3462101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:33:05
User entered empty.		11 Aug 2020 00:03:12

US3462101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

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 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:32:39
User entered empty.		11 Aug 2020 00:03:12

US3462101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 00:03:12

US3462101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:31:36
User entered '10 Aug 2020'		11 Aug 2020 00:03:12

US3462101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:31:45
User entered '16:48' reason for change: Data Entry Error		11 Aug 2020 00:12:20
User entered empty.		11 Aug 2020 00:03:12

US3462101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered '10 Aug 2020 16:48'	System	11 Aug 2020 00:12:20
User entered empty.	System	11 Aug 2020 00:03:12

US3462101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:32:27
User entered 'Right Arm (RIGHT ARM)'		11 Aug 2020 00:03:12

US3462101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
DataPoint Verified.		23 Sep 2020 17:32:29
User entered 'ONCE'	System	11 Aug 2020 00:03:12

US3462101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 00:03:12

US3462101

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:37:58
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:19

US3462101

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:37:59
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:19

US3462101

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:38:01
User entered '16:37'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:19

US3462101

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered '10 Aug 2020 16:37'	System	13 Aug 2020 17:13:19

US3462101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:39:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:11:00
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:39

US3462101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:39

US3462101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:38:20
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:39

US3462101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:54

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:38:29
User entered '16:39'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:39

US3462101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered '10 Aug 2020 16:39'	System	13 Aug 2020 17:13:39

US3462101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:39

US3462101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:38:36
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:39

US3462101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:38:38
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:39

US3462101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered empty.	System	13 Aug 2020 17:13:39

US3462101

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:38:45
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:13:43

US3462101

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'I'	System	13 Aug 2020 17:13:43

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:20:48', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '38845234-1c43-4a2d-b912-6a63952faa36'	System	11 Aug 2020 00:21:05
User entered 'Yes (Y)'	System	11 Aug 2020 00:21:05

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:20:53', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '38845234-1c43-4a2d-b912-6a63952faa36'	System	11 Aug 2020 00:21:05
User entered '97.7'	System	11 Aug 2020 00:21:05

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:20:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '38845234-1c43-4a2d-b912-6a63952faa36'	System	11 Aug 2020 00:21:05
User entered 'No (N)'	System	11 Aug 2020 00:21:05

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '38845234-1c43-4a2d-b912-6a63952faa36'	System	11 Aug 2020 00:21:05
User entered '10 Aug 2020 17:21'	System	11 Aug 2020 00:21:05

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Aug 2020 17:08'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Aug 2020 19:38'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:07', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6c8e7449-e392-4395-a8e5-4d5e98e61a57'	System	11 Aug 2020 03:34:24
User entered 'Yes (Y)'	System	11 Aug 2020 03:34:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:12', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6c8e7449-e392-4395-a8e5-4d5e98e61a57'	System	11 Aug 2020 03:34:24
User entered '97.7'	System	11 Aug 2020 03:34:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:15', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6c8e7449-e392-4395-a8e5-4d5e98e61a57'	System	11 Aug 2020 03:34:24
User entered 'No (N)'	System	11 Aug 2020 03:34:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:18', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6c8e7449-e392-4395-a8e5-4d5e98e61a57'	System	11 Aug 2020 03:34:24
User entered '10 Aug 2020 20:34'	System	11 Aug 2020 03:34:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Aug 2020 20:33'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 2'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:50:52', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '37eb6969-0a97-439e-8d89-c7f535589e33'	System	12 Aug 2020 01:51:10
User entered 'Yes (Y)'	System	12 Aug 2020 01:51:10

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:50:58', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '37eb6969-0a97-439e-8d89-c7f535589e33'	System	12 Aug 2020 01:51:10
User entered '97.5'	System	12 Aug 2020 01:51:10

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:02', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '37eb6969-0a97-439e-8d89-c7f535589e33'	System	12 Aug 2020 01:51:10
User entered 'No (N)'	System	12 Aug 2020 01:51:10

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:05', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '37eb6969-0a97-439e-8d89-c7f535589e33'	System	12 Aug 2020 01:51:10
User entered '11 Aug 2020 18:51'	System	12 Aug 2020 01:51:10

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 3'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:10', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'ec21232b-70f7-4eec-a52b-f8eea7f00f1d'	System	12 Aug 2020 20:21:24
User entered 'Yes (Y)'	System	12 Aug 2020 20:21:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:14', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'ec21232b-70f7-4eec-a52b-f8eea7f00f1d'	System	12 Aug 2020 20:21:24
User entered '98.6'	System	12 Aug 2020 20:21:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:17', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'ec21232b-70f7-4eec-a52b-f8eea7f00f1d'	System	12 Aug 2020 20:21:24
User entered 'No (N)'	System	12 Aug 2020 20:21:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:19', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'ec21232b-70f7-4eec-a52b-f8eea7f00f1d'	System	12 Aug 2020 20:21:24
User entered '12 Aug 2020 13:21'	System	12 Aug 2020 20:21:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 4'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:09', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5f16a504-69bc-4656-991d-3ffad56a83e7'	System	14 Aug 2020 03:01:24
User entered 'Yes (Y)'	System	14 Aug 2020 03:01:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:16', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5f16a504-69bc-4656-991d-3ffad56a83e7'	System	14 Aug 2020 03:01:24
User entered '98.6'	System	14 Aug 2020 03:01:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:19', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5f16a504-69bc-4656-991d-3ffad56a83e7'	System	14 Aug 2020 03:01:24
User entered 'No (N)'	System	14 Aug 2020 03:01:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:22', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5f16a504-69bc-4656-991d-3ffad56a83e7'	System	14 Aug 2020 03:01:24
User entered '13 Aug 2020 20:01'	System	14 Aug 2020 03:01:24

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 5'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:44:46', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '74d7020a-155f-40ca-b8be-8cd9ad48295d'	System	14 Aug 2020 19:44:58
User entered 'Yes (Y)'	System	14 Aug 2020 19:44:58

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:44:50', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '74d7020a-155f-40ca-b8be-8cd9ad48295d'	System	14 Aug 2020 19:44:58
User entered '98.1'	System	14 Aug 2020 19:44:58

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:44:52', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '74d7020a-155f-40ca-b8be-8cd9ad48295d'	System	14 Aug 2020 19:44:58
User entered 'No (N)'	System	14 Aug 2020 19:44:58

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:44:55', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '74d7020a-155f-40ca-b8be-8cd9ad48295d'	System	14 Aug 2020 19:44:58
User entered '14 Aug 2020 12:44'	System	14 Aug 2020 19:44:58

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 6'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:15:22', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'fffb67a3-668f-4507-a925-63411d0c1bb8'	System	16 Aug 2020 00:15:38
User entered 'Yes (Y)'	System	16 Aug 2020 00:15:38

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:15:27', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'fffb67a3-668f-4507-a925-63411d0c1bb8'	System	16 Aug 2020 00:15:38
User entered '97.8'	System	16 Aug 2020 00:15:38

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:15:30', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'fffb67a3-668f-4507-a925-63411d0c1bb8'	System	16 Aug 2020 00:15:38
User entered 'No (N)'	System	16 Aug 2020 00:15:38

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:15:34', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'fffb67a3-668f-4507-a925-63411d0c1bb8'	System	16 Aug 2020 00:15:38
User entered '15 Aug 2020 17:15'	System	16 Aug 2020 00:15:38

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 7'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:19', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3a6f9176-d099-4b8e-bd21-19ec7bb0e8b9'	System	16 Aug 2020 23:53:31
User entered 'Yes (Y)'	System	16 Aug 2020 23:53:31

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:23', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3a6f9176-d099-4b8e-bd21-19ec7bb0e8b9'	System	16 Aug 2020 23:53:31
User entered '97.9'	System	16 Aug 2020 23:53:31

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:26', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3a6f9176-d099-4b8e-bd21-19ec7bb0e8b9'	System	16 Aug 2020 23:53:31
User entered 'No (N)'	System	16 Aug 2020 23:53:31

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:29', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3a6f9176-d099-4b8e-bd21-19ec7bb0e8b9'	System	16 Aug 2020 23:53:31
User entered '16 Aug 2020 16:53'	System	16 Aug 2020 23:53:31

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:09', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '21f97dad-ed63-4d5c-9df6-24c78a5e7c82'	System	11 Aug 2020 00:21:31
User entered 'None (1)'	System	11 Aug 2020 00:21:31

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:18', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '21f97dad-ed63-4d5c-9df6-24c78a5e7c82'	System	11 Aug 2020 00:21:31
User entered 'No (N)'	System	11 Aug 2020 00:21:31

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:20', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '21f97dad-ed63-4d5c-9df6-24c78a5e7c82'	System	11 Aug 2020 00:21:31
User entered 'No (N)'	System	11 Aug 2020 00:21:31

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:24', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '21f97dad-ed63-4d5c-9df6-24c78a5e7c82'	System	11 Aug 2020 00:21:31
User entered 'None (1)'	System	11 Aug 2020 00:21:31

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:27', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '21f97dad-ed63-4d5c-9df6-24c78a5e7c82'	System	11 Aug 2020 00:21:31
User entered '10 Aug 2020 17:21'	System	11 Aug 2020 00:21:31

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Aug 2020 17:08'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Aug 2020 19:38'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:22', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0f6d385b-0548-48db-a4b6-526b6440bffc'	System	11 Aug 2020 03:34:40
User entered 'None (1)'	System	11 Aug 2020 03:34:40

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:26', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0f6d385b-0548-48db-a4b6-526b6440bffc'	System	11 Aug 2020 03:34:40
User entered 'No (N)'	System	11 Aug 2020 03:34:40

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:30', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0f6d385b-0548-48db-a4b6-526b6440bffc'	System	11 Aug 2020 03:34:40
User entered 'No (N)'	System	11 Aug 2020 03:34:40

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:33', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0f6d385b-0548-48db-a4b6-526b6440bffc'	System	11 Aug 2020 03:34:40
User entered 'None (1)'	System	11 Aug 2020 03:34:40

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:36', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0f6d385b-0548-48db-a4b6-526b6440bffc'	System	11 Aug 2020 03:34:40
User entered '10 Aug 2020 20:34'	System	11 Aug 2020 03:34:40

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Aug 2020 20:33'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 2'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:18', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '46efcf5f-8a18-4987-bfbd-52f0d11b0272'	System	12 Aug 2020 01:51:34
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 01:51:34

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:20', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '46efcf5f-8a18-4987-bfbd-52f0d11b0272'	System	12 Aug 2020 01:51:34
User entered 'No (N)'	System	12 Aug 2020 01:51:34

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:26', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '46efcf5f-8a18-4987-bfbd-52f0d11b0272'	System	12 Aug 2020 01:51:34
User entered 'No (N)'	System	12 Aug 2020 01:51:34

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:29', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '46efcf5f-8a18-4987-bfbd-52f0d11b0272'	System	12 Aug 2020 01:51:34
User entered 'None (1)'	System	12 Aug 2020 01:51:34

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:32', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '46efcf5f-8a18-4987-bfbd-52f0d11b0272'	System	12 Aug 2020 01:51:34
User entered '11 Aug 2020 18:51'	System	12 Aug 2020 01:51:34

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 3'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:25', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e63b6c5d-9ed3-480f-a4e0-82eca9f0160a'	System	12 Aug 2020 20:21:46
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 20:21:46

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:27', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e63b6c5d-9ed3-480f-a4e0-82eca9f0160a'	System	12 Aug 2020 20:21:46
User entered 'No (N)'	System	12 Aug 2020 20:21:46

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:30', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e63b6c5d-9ed3-480f-a4e0-82eca9f0160a'	System	12 Aug 2020 20:21:46
User entered 'No (N)'	System	12 Aug 2020 20:21:46

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:34', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e63b6c5d-9ed3-480f-a4e0-82eca9f0160a'	System	12 Aug 2020 20:21:46
User entered 'None (1)'	System	12 Aug 2020 20:21:46

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:43', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e63b6c5d-9ed3-480f-a4e0-82eca9f0160a'	System	12 Aug 2020 20:21:46
User entered '12 Aug 2020 13:21'	System	12 Aug 2020 20:21:46

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 4'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:30', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e4e67e49-8f83-404d-818e-46b0708cbaf2'	System	14 Aug 2020 03:01:43
User entered 'None (1)'	System	14 Aug 2020 03:01:43

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:33', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e4e67e49-8f83-404d-818e-46b0708cbaf2'	System	14 Aug 2020 03:01:43
User entered 'No (N)'	System	14 Aug 2020 03:01:43

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:35', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e4e67e49-8f83-404d-818e-46b0708cbaf2'	System	14 Aug 2020 03:01:43
User entered 'No (N)'	System	14 Aug 2020 03:01:43

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:38', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e4e67e49-8f83-404d-818e-46b0708cbaf2'	System	14 Aug 2020 03:01:43
User entered 'None (1)'	System	14 Aug 2020 03:01:43

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:40', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e4e67e49-8f83-404d-818e-46b0708cbaf2'	System	14 Aug 2020 03:01:43
User entered '13 Aug 2020 20:01'	System	14 Aug 2020 03:01:43

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 5'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:44:59', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b9f33372-b4fb-4f6c-a5d9-4ac321ae6e21'	System	14 Aug 2020 19:45:42
User entered 'None (1)'	System	14 Aug 2020 19:45:42

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:30', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b9f33372-b4fb-4f6c-a5d9-4ac321ae6e21'	System	14 Aug 2020 19:45:42
User entered 'No (N)'	System	14 Aug 2020 19:45:42

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:32', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b9f33372-b4fb-4f6c-a5d9-4ac321ae6e21'	System	14 Aug 2020 19:45:42
User entered 'No (N)'	System	14 Aug 2020 19:45:42

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:35', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b9f33372-b4fb-4f6c-a5d9-4ac321ae6e21'	System	14 Aug 2020 19:45:42
User entered 'None (1)'	System	14 Aug 2020 19:45:42

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:38', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b9f33372-b4fb-4f6c-a5d9-4ac321ae6e21'	System	14 Aug 2020 19:45:42
User entered '14 Aug 2020 12:45'	System	14 Aug 2020 19:45:42

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 6'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:15:39', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7ef11f77-d3e7-4d98-a32a-1c92fe99a8f8'	System	16 Aug 2020 00:16:01
User entered 'None (1)'	System	16 Aug 2020 00:16:01

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:15:42', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7ef11f77-d3e7-4d98-a32a-1c92fe99a8f8'	System	16 Aug 2020 00:16:01
User entered 'No (N)'	System	16 Aug 2020 00:16:01

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:15:44', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7ef11f77-d3e7-4d98-a32a-1c92fe99a8f8'	System	16 Aug 2020 00:16:01
User entered 'No (N)'	System	16 Aug 2020 00:16:01

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:15:46', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7ef11f77-d3e7-4d98-a32a-1c92fe99a8f8'	System	16 Aug 2020 00:16:01
User entered 'None (1)'	System	16 Aug 2020 00:16:01

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:15:57', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7ef11f77-d3e7-4d98-a32a-1c92fe99a8f8'	System	16 Aug 2020 00:16:01
User entered '15 Aug 2020 17:15'	System	16 Aug 2020 00:16:01

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 7'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:34', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f25c5028-32f3-4fad-8acc-b4ebd185543c'	System	16 Aug 2020 23:53:47
User entered 'None (1)'	System	16 Aug 2020 23:53:47

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:37', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f25c5028-32f3-4fad-8acc-b4ebd185543c'	System	16 Aug 2020 23:53:47
User entered 'No (N)'	System	16 Aug 2020 23:53:47

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:39', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f25c5028-32f3-4fad-8acc-b4ebd185543c'	System	16 Aug 2020 23:53:47
User entered 'No (N)'	System	16 Aug 2020 23:53:47

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:41', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f25c5028-32f3-4fad-8acc-b4ebd185543c'	System	16 Aug 2020 23:53:47
User entered 'None (1)'	System	16 Aug 2020 23:53:47

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:43', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f25c5028-32f3-4fad-8acc-b4ebd185543c'	System	16 Aug 2020 23:53:47
User entered '16 Aug 2020 16:53'	System	16 Aug 2020 23:53:47

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:32', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e8f55f1e-006f-4dd7-9c68-86be43ab8744'	System	11 Aug 2020 00:21:52
User entered 'None (0)'	System	11 Aug 2020 00:21:52

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:35', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e8f55f1e-006f-4dd7-9c68-86be43ab8744'	System	11 Aug 2020 00:21:52
User entered 'None (0)'	System	11 Aug 2020 00:21:52

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:37', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e8f55f1e-006f-4dd7-9c68-86be43ab8744'	System	11 Aug 2020 00:21:52
User entered 'None (0)'	System	11 Aug 2020 00:21:52

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:39', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e8f55f1e-006f-4dd7-9c68-86be43ab8744'	System	11 Aug 2020 00:21:52
User entered 'None (0)'	System	11 Aug 2020 00:21:52

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:40', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e8f55f1e-006f-4dd7-9c68-86be43ab8744'	System	11 Aug 2020 00:21:52
User entered 'None (0)'	System	11 Aug 2020 00:21:52

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:43', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e8f55f1e-006f-4dd7-9c68-86be43ab8744'	System	11 Aug 2020 00:21:52
User entered 'None (0)'	System	11 Aug 2020 00:21:52

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:46', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e8f55f1e-006f-4dd7-9c68-86be43ab8744'	System	11 Aug 2020 00:21:52
User entered 'No (N)'	System	11 Aug 2020 00:21:52

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T17:21:48', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e8f55f1e-006f-4dd7-9c68-86be43ab8744'	System	11 Aug 2020 00:21:52
User entered '10 Aug 2020 17:21'	System	11 Aug 2020 00:21:52

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Aug 2020 17:08'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Aug 2020 19:38'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:41', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '47a96f9c-ec38-43d7-a505-fc85067f22ac'	System	11 Aug 2020 03:35:01
User entered 'None (0)'	System	11 Aug 2020 03:35:01

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:44', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '47a96f9c-ec38-43d7-a505-fc85067f22ac'	System	11 Aug 2020 03:35:01
User entered 'None (0)'	System	11 Aug 2020 03:35:01

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:46', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '47a96f9c-ec38-43d7-a505-fc85067f22ac'	System	11 Aug 2020 03:35:01
User entered 'None (0)'	System	11 Aug 2020 03:35:01

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:47', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '47a96f9c-ec38-43d7-a505-fc85067f22ac'	System	11 Aug 2020 03:35:01
User entered 'None (0)'	System	11 Aug 2020 03:35:01

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:49', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '47a96f9c-ec38-43d7-a505-fc85067f22ac'	System	11 Aug 2020 03:35:01
User entered 'None (0)'	System	11 Aug 2020 03:35:01

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:51', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '47a96f9c-ec38-43d7-a505-fc85067f22ac'	System	11 Aug 2020 03:35:01
User entered 'None (0)'	System	11 Aug 2020 03:35:01

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:54', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '47a96f9c-ec38-43d7-a505-fc85067f22ac'	System	11 Aug 2020 03:35:01
User entered 'No (N)'	System	11 Aug 2020 03:35:01

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-10T20:34:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '47a96f9c-ec38-43d7-a505-fc85067f22ac'	System	11 Aug 2020 03:35:01
User entered '10 Aug 2020 20:34'	System	11 Aug 2020 03:35:01

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Aug 2020 20:33'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 2'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:39', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a429b705-9c39-40c1-8446-2eef69cc8166'	System	12 Aug 2020 01:52:05
User entered 'None (0)'	System	12 Aug 2020 01:52:05

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:42', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a429b705-9c39-40c1-8446-2eef69cc8166'	System	12 Aug 2020 01:52:05
User entered 'None (0)'	System	12 Aug 2020 01:52:05

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:45', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a429b705-9c39-40c1-8446-2eef69cc8166'	System	12 Aug 2020 01:52:05
User entered 'None (0)'	System	12 Aug 2020 01:52:05

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:48', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a429b705-9c39-40c1-8446-2eef69cc8166'	System	12 Aug 2020 01:52:05
User entered 'None (0)'	System	12 Aug 2020 01:52:05

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:51', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a429b705-9c39-40c1-8446-2eef69cc8166'	System	12 Aug 2020 01:52:05
User entered 'None (0)'	System	12 Aug 2020 01:52:05

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:54', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a429b705-9c39-40c1-8446-2eef69cc8166'	System	12 Aug 2020 01:52:05
User entered 'None (0)'	System	12 Aug 2020 01:52:05

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:51:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a429b705-9c39-40c1-8446-2eef69cc8166'	System	12 Aug 2020 01:52:05
User entered 'No (N)'	System	12 Aug 2020 01:52:05

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-11T18:52:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a429b705-9c39-40c1-8446-2eef69cc8166'	System	12 Aug 2020 01:52:05
User entered '11 Aug 2020 18:52'	System	12 Aug 2020 01:52:05

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 3'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:49', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '97d10b16-76bd-489c-a405-22fb4291f224'	System	12 Aug 2020 20:22:13
User entered 'None (0)'	System	12 Aug 2020 20:22:13

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:51', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '97d10b16-76bd-489c-a405-22fb4291f224'	System	12 Aug 2020 20:22:13
User entered 'None (0)'	System	12 Aug 2020 20:22:13

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:54', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '97d10b16-76bd-489c-a405-22fb4291f224'	System	12 Aug 2020 20:22:13
User entered 'None (0)'	System	12 Aug 2020 20:22:13

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:21:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '97d10b16-76bd-489c-a405-22fb4291f224'	System	12 Aug 2020 20:22:13
User entered 'None (0)'	System	12 Aug 2020 20:22:13

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:22:03', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '97d10b16-76bd-489c-a405-22fb4291f224'	System	12 Aug 2020 20:22:13
User entered 'None (0)'	System	12 Aug 2020 20:22:13

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:22:05', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '97d10b16-76bd-489c-a405-22fb4291f224'	System	12 Aug 2020 20:22:13
User entered 'None (0)'	System	12 Aug 2020 20:22:13

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:22:07', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '97d10b16-76bd-489c-a405-22fb4291f224'	System	12 Aug 2020 20:22:13
User entered 'No (N)'	System	12 Aug 2020 20:22:13

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-12T13:22:10', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '97d10b16-76bd-489c-a405-22fb4291f224'	System	12 Aug 2020 20:22:13
User entered '12 Aug 2020 13:22'	System	12 Aug 2020 20:22:13

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 4'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:46', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a7338624-1072-4038-ba8a-1cf290bc3642'	System	14 Aug 2020 03:02:09
User entered 'None (0)'	System	14 Aug 2020 03:02:09

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:51', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a7338624-1072-4038-ba8a-1cf290bc3642'	System	14 Aug 2020 03:02:09
User entered 'Significant; prevents daily activity (3)'	System	14 Aug 2020 03:02:09

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:53', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a7338624-1072-4038-ba8a-1cf290bc3642'	System	14 Aug 2020 03:02:09
User entered 'None (0)'	System	14 Aug 2020 03:02:09

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a7338624-1072-4038-ba8a-1cf290bc3642'	System	14 Aug 2020 03:02:09
User entered 'None (0)'	System	14 Aug 2020 03:02:09

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:01:58', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a7338624-1072-4038-ba8a-1cf290bc3642'	System	14 Aug 2020 03:02:09
User entered 'None (0)'	System	14 Aug 2020 03:02:09

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:02:01', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a7338624-1072-4038-ba8a-1cf290bc3642'	System	14 Aug 2020 03:02:09
User entered 'None (0)'	System	14 Aug 2020 03:02:09

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:02:03', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a7338624-1072-4038-ba8a-1cf290bc3642'	System	14 Aug 2020 03:02:09
User entered 'No (N)'	System	14 Aug 2020 03:02:09

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-13T20:02:06', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a7338624-1072-4038-ba8a-1cf290bc3642'	System	14 Aug 2020 03:02:09
User entered '13 Aug 2020 20:02'	System	14 Aug 2020 03:02:09

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 5'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:42', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '20b803ab-87f2-4f95-9a80-45b32ebd5a6e'	System	14 Aug 2020 19:46:07
User entered 'None (0)'	System	14 Aug 2020 19:46:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:47', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '20b803ab-87f2-4f95-9a80-45b32ebd5a6e'	System	14 Aug 2020 19:46:07
User entered 'No interference with activity (1)'	System	14 Aug 2020 19:46:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:50', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '20b803ab-87f2-4f95-9a80-45b32ebd5a6e'	System	14 Aug 2020 19:46:07
User entered 'None (0)'	System	14 Aug 2020 19:46:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:52', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '20b803ab-87f2-4f95-9a80-45b32ebd5a6e'	System	14 Aug 2020 19:46:07
User entered 'None (0)'	System	14 Aug 2020 19:46:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:54', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '20b803ab-87f2-4f95-9a80-45b32ebd5a6e'	System	14 Aug 2020 19:46:07
User entered 'None (0)'	System	14 Aug 2020 19:46:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '20b803ab-87f2-4f95-9a80-45b32ebd5a6e'	System	14 Aug 2020 19:46:07
User entered 'None (0)'	System	14 Aug 2020 19:46:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:45:58', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '20b803ab-87f2-4f95-9a80-45b32ebd5a6e'	System	14 Aug 2020 19:46:07
User entered 'No (N)'	System	14 Aug 2020 19:46:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-14T12:46:01', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '20b803ab-87f2-4f95-9a80-45b32ebd5a6e'	System	14 Aug 2020 19:46:07
User entered '14 Aug 2020 12:46'	System	14 Aug 2020 19:46:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 6'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:16:04', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0d30e546-28ba-4019-a38c-63b657c2d06b'	System	16 Aug 2020 00:16:25
User entered 'None (0)'	System	16 Aug 2020 00:16:25

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:16:07', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0d30e546-28ba-4019-a38c-63b657c2d06b'	System	16 Aug 2020 00:16:25
User entered 'None (0)'	System	16 Aug 2020 00:16:25

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:16:10', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0d30e546-28ba-4019-a38c-63b657c2d06b'	System	16 Aug 2020 00:16:25
User entered 'None (0)'	System	16 Aug 2020 00:16:25

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:16:11', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0d30e546-28ba-4019-a38c-63b657c2d06b'	System	16 Aug 2020 00:16:25
User entered 'None (0)'	System	16 Aug 2020 00:16:25

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:16:13', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0d30e546-28ba-4019-a38c-63b657c2d06b'	System	16 Aug 2020 00:16:25
User entered 'None (0)'	System	16 Aug 2020 00:16:25

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:16:15', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0d30e546-28ba-4019-a38c-63b657c2d06b'	System	16 Aug 2020 00:16:25
User entered 'None (0)'	System	16 Aug 2020 00:16:25

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:16:20', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0d30e546-28ba-4019-a38c-63b657c2d06b'	System	16 Aug 2020 00:16:25
User entered 'No (N)'	System	16 Aug 2020 00:16:25

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-15T17:16:22', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '0d30e546-28ba-4019-a38c-63b657c2d06b'	System	16 Aug 2020 00:16:25
User entered '15 Aug 2020 17:16'	System	16 Aug 2020 00:16:25

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 7'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:50', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e347318b-acd3-45af-a443-48c7a14236cd'	System	16 Aug 2020 23:54:07
User entered 'None (0)'	System	16 Aug 2020 23:54:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:52', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e347318b-acd3-45af-a443-48c7a14236cd'	System	16 Aug 2020 23:54:07
User entered 'None (0)'	System	16 Aug 2020 23:54:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:54', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e347318b-acd3-45af-a443-48c7a14236cd'	System	16 Aug 2020 23:54:07
User entered 'None (0)'	System	16 Aug 2020 23:54:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e347318b-acd3-45af-a443-48c7a14236cd'	System	16 Aug 2020 23:54:07
User entered 'None (0)'	System	16 Aug 2020 23:54:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:53:58', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e347318b-acd3-45af-a443-48c7a14236cd'	System	16 Aug 2020 23:54:07
User entered 'None (0)'	System	16 Aug 2020 23:54:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:54:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e347318b-acd3-45af-a443-48c7a14236cd'	System	16 Aug 2020 23:54:07
User entered 'None (0)'	System	16 Aug 2020 23:54:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:54:03', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e347318b-acd3-45af-a443-48c7a14236cd'	System	16 Aug 2020 23:54:07
User entered 'No (N)'	System	16 Aug 2020 23:54:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-08-16T16:54:05', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e347318b-acd3-45af-a443-48c7a14236cd'	System	16 Aug 2020 23:54:07
User entered '16 Aug 2020 16:54'	System	16 Aug 2020 23:54:07

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:12:20

US3462101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:27
User entered 'Yes (Y)'		05 Sep 2020 16:34:35

US3462101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:30
User entered '17 Aug 2020'		05 Sep 2020 16:34:35

US3462101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:37
User entered 'Contact Made (CONTACT MADE)'		05 Sep 2020 16:34:35

US3462101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:41:39
User entered empty.		05 Sep 2020 16:34:35

US3462101

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:42:34
User entered 'Yes (Y)'		05 Sep 2020 16:39:40

US3462101

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'I'	System	05 Sep 2020 16:39:40

US3462101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	23 Sep 2020 17:44:23
User entered 'Yes (Y)'		05 Sep 2020 16:40:17

US3462101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:24
User entered '24 Aug 2020'		05 Sep 2020 16:40:17

US3462101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:26
User entered 'Contact Made (CONTACT MADE)'		05 Sep 2020 16:40:17

US3462101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:28
User entered empty.		05 Sep 2020 16:40:17

US3462101

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:36
User entered 'Yes (Y)'		05 Sep 2020 16:45:18

US3462101

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:57
User entered 'I'	System	05 Sep 2020 16:45:18

US3462101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:59
User entered 'Yes (Y)'		05 Sep 2020 16:46:11

US3462101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	23 Sep 2020 17:45:01
User entered '31 Aug 2020'		05 Sep 2020 16:46:11

US3462101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Sep 2020 17:45:03
User entered 'Contact Made (CONTACT MADE)'		05 Sep 2020 16:46:11

US3462101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:04
User entered empty.		05 Sep 2020 16:46:11

US3462101

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:31
User entered 'Yes (Y)'		05 Sep 2020 16:46:34

US3462101

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User entered 'I'	System	05 Sep 2020 16:46:34

US3462101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:49:02
User entered 'Yes (Y)'		10 Sep 2020 22:49:38

US3462101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:49:04
User entered '10 Sep 2020'		10 Sep 2020 22:49:38

US3462101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[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 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:49:06
User entered 'Clinic (Clinic)'		10 Sep 2020 22:49:38

US3462101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'VISIT2'	System	10 Sep 2020 22:49:38

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:50:03
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:50:05
User entered '10 Sep 2020'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:50:07
User entered '15:46'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered '10 Sep 2020 15:46'	System	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:50:13
User entered '36.4' C	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:50:15
User entered 'Other (Other)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:50:17
User entered 'Tympanic'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:50:20
User entered '80'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'bpm'	System	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:50:23
User entered '14'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'breaths/min'	System	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:50:25
User entered '143'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'mmHg'	System	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:50:28
User entered '89'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:39:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'mmHg'	System	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:02:22
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:02:11
User entered '10 Sep 2020'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:02:09
User entered '16:46'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered '10 Sep 2020 16:46'	System	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:02:35
User entered '36.3' C	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:02:44
User entered 'Other (Other)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:05:51
User entered 'Tympanic'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:05:55
User entered '82'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'bpm'	System	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:05:58
User entered '12'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'breaths/min'	System	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:06:01
User entered '130'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'mmHg'	System	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:06:02
User entered '90'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:39:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'mmHg'	System	19 Sep 2020 00:40:37

US3462101

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:08:11
User entered 'No (N)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:43

US3462101

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:08:13
User entered empty.	Danuel Hamlin (b) (4)	19 Sep 2020 00:40:43

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:09:24
User entered 'Yes (Y)'		10 Sep 2020 23:16:07

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:09:25
User entered empty.		10 Sep 2020 23:16:07

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

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 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:10:47
User entered empty.		10 Sep 2020 23:16:07

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 23:16:07

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:09:15
User entered '10 Sep 2020'		10 Sep 2020 23:16:07

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:09:17
User entered '16:15'		10 Sep 2020 23:16:07

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered '10 Sep 2020 16:15'	System	10 Sep 2020 23:16:07

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:09:18
User entered 'Right Arm (RIGHT ARM)'		10 Sep 2020 23:16:07

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
DataPoint Verified.		23 Sep 2020 18:09:20
User entered 'ONCE'	System	10 Sep 2020 23:16:07

US3462101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:39:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 23:16:07

US3462101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:11:05
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:41:10

US3462101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:11:10
User entered '10 Sep 2020'	Danuel Hamlin (b) (4)	19 Sep 2020 00:41:10

US3462101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:11:12
User entered '16:05'	Danuel Hamlin (b) (4)	19 Sep 2020 00:41:10

US3462101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered '10 Sep 2020 16:05'	System	19 Sep 2020 00:41:10

US3462101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:39:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:18:51
User entered '10 Sep 2020'	Danuel Hamlin (b) (4)	19 Sep 2020 00:41:30

US3462101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:41:30

US3462101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:12:22
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:41:30

US3462101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:54

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:12:26
User entered '16:07'	Danuel Hamlin (b) (4)	19 Sep 2020 00:41:30

US3462101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:39:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered '10 Sep 2020 16:07'	System	19 Sep 2020 00:41:30

US3462101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User closed query 'Swab 2 is not in source document. Please verify and update accordingly.' (Site from CRA).		19 Nov 2020 00:18:48
Query 'Swab 2 is not in source document. Please verify and update accordingly.' answered with 'ENTRY ERROR' (Site from CRA).		09 Oct 2020 19:45:52
User opened query 'Swab 2 is not in source document. Please verify and update accordingly.' (Site from CRA).		23 Sep 2020 18:13:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:41:30

US3462101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:51
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 19:45:37
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	19 Sep 2020 00:41:30

US3462101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:18:51
User entered empty; reason for change Data Entry Error		09 Oct 2020 19:45:37
User entered '16:07'	Danuel Hamlin (b) (4)	19 Sep 2020 00:41:30

US3462101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:39:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered empty.	System	09 Oct 2020 19:45:37
User entered '10 Sep 2020 16:07'	System	19 Sep 2020 00:41:30

US3462101

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:14:58
User entered 'Yes (Y)'		10 Sep 2020 23:16:17

US3462101

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'I'	System	10 Sep 2020 23:16:17

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:42:45', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '4ba003a9-6866-466c-842e-ab15392260ae'	System	10 Sep 2020 23:43:01
User entered 'Yes (Y)'	System	10 Sep 2020 23:43:01

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:42:50', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '4ba003a9-6866-466c-842e-ab15392260ae'	System	10 Sep 2020 23:43:01
User entered '97.3'	System	10 Sep 2020 23:43:01

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:42:53', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '4ba003a9-6866-466c-842e-ab15392260ae'	System	10 Sep 2020 23:43:01
User entered 'No (N)'	System	10 Sep 2020 23:43:01

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:42:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '4ba003a9-6866-466c-842e-ab15392260ae'	System	10 Sep 2020 23:43:01
User entered '10 Sep 2020 16:42'	System	10 Sep 2020 23:43:01

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Sep 2020 16:35'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Sep 2020 19:05'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:25', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f07f4351-e76c-4a40-aaae-731fba624c9d'	System	11 Sep 2020 03:00:37
User entered 'Yes (Y)'	System	11 Sep 2020 03:00:37

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:28', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f07f4351-e76c-4a40-aaae-731fba624c9d'	System	11 Sep 2020 03:00:37
User entered '97.3'	System	11 Sep 2020 03:00:37

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:31', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f07f4351-e76c-4a40-aaae-731fba624c9d'	System	11 Sep 2020 03:00:37
User entered 'No (N)'	System	11 Sep 2020 03:00:37

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:33', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f07f4351-e76c-4a40-aaae-731fba624c9d'	System	11 Sep 2020 03:00:37
User entered '10 Sep 2020 20:00'	System	11 Sep 2020 03:00:37

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Sep 2020 20:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 2'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:32:37', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c57ed898-36a7-453f-b0cd-95a4991b3f9c'	System	12 Sep 2020 01:33:01
User entered 'Yes (Y)'	System	12 Sep 2020 01:33:01

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:32:41', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c57ed898-36a7-453f-b0cd-95a4991b3f9c'	System	12 Sep 2020 01:33:01
User entered '98.6'	System	12 Sep 2020 01:33:01

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:32:45', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c57ed898-36a7-453f-b0cd-95a4991b3f9c'	System	12 Sep 2020 01:33:01
User entered 'Yes (Y)'	System	12 Sep 2020 01:33:01

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject used 500mg Tylenol and Advil 600mg once on day2 for pain' (Site from System).		20 Oct 2020 11:46:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Sep 2020 01:33:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:32:50', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c57ed898-36a7-453f-b0cd-95a4991b3f9c'	System	12 Sep 2020 01:33:01
User entered '1'	System	12 Sep 2020 01:33:01

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:32:50', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c57ed898-36a7-453f-b0cd-95a4991b3f9c'	System	12 Sep 2020 01:33:01
User entered '0'	System	12 Sep 2020 01:33:01

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:32:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c57ed898-36a7-453f-b0cd-95a4991b3f9c'	System	12 Sep 2020 01:33:01
User entered '11 Sep 2020 18:32'	System	12 Sep 2020 01:33:01

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 3'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:31:53', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '34218076-5c23-494a-985c-4560c59769f8'	System	12 Sep 2020 23:32:51
User entered 'Yes (Y)'	System	12 Sep 2020 23:32:51

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:31:58', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '34218076-5c23-494a-985c-4560c59769f8'	System	12 Sep 2020 23:32:51
User entered '97.5'	System	12 Sep 2020 23:32:51

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '34218076-5c23-494a-985c-4560c59769f8'	System	12 Sep 2020 23:32:51
User entered 'No (N)'	System	12 Sep 2020 23:32:51

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:03', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '34218076-5c23-494a-985c-4560c59769f8'	System	12 Sep 2020 23:32:51
User entered '12 Sep 2020 16:32'	System	12 Sep 2020 23:32:51

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 4'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a810077a-2733-400c-863b-4d88ce5da06d'	System	14 Sep 2020 03:29:12
User entered 'Yes (Y)'	System	14 Sep 2020 03:29:12

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:04', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a810077a-2733-400c-863b-4d88ce5da06d'	System	14 Sep 2020 03:29:12
User entered '97.9'	System	14 Sep 2020 03:29:12

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:07', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a810077a-2733-400c-863b-4d88ce5da06d'	System	14 Sep 2020 03:29:12
User entered 'No (N)'	System	14 Sep 2020 03:29:12

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:09', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a810077a-2733-400c-863b-4d88ce5da06d'	System	14 Sep 2020 03:29:12
User entered '13 Sep 2020 20:29'	System	14 Sep 2020 03:29:12

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 5'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T22:59:48', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '81f05c11-8ab7-4feb-814e-a5c7f75dde9b'	System	15 Sep 2020 06:03:51
User entered 'Yes (Y)'	System	15 Sep 2020 06:03:51

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:03:44', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '81f05c11-8ab7-4feb-814e-a5c7f75dde9b'	System	15 Sep 2020 06:03:51
User entered '97.9'	System	15 Sep 2020 06:03:51

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:03:46', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '81f05c11-8ab7-4feb-814e-a5c7f75dde9b'	System	15 Sep 2020 06:03:51
User entered 'No (N)'	System	15 Sep 2020 06:03:51

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:03:49', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '81f05c11-8ab7-4feb-814e-a5c7f75dde9b'	System	15 Sep 2020 06:03:51
User entered '14 Sep 2020 23:03'	System	15 Sep 2020 06:03:51

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 6'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:47:42', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '2c872bd7-c2ac-40cc-bc17-b09b3df73ccd'	System	16 Sep 2020 04:47:54
User entered 'Yes (Y)'	System	16 Sep 2020 04:47:54

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:47:46', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '2c872bd7-c2ac-40cc-bc17-b09b3df73ccd'	System	16 Sep 2020 04:47:54
User entered '98.4'	System	16 Sep 2020 04:47:54

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:47:48', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '2c872bd7-c2ac-40cc-bc17-b09b3df73ccd'	System	16 Sep 2020 04:47:54
User entered 'No (N)'	System	16 Sep 2020 04:47:54

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:47:50', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '2c872bd7-c2ac-40cc-bc17-b09b3df73ccd'	System	16 Sep 2020 04:47:54
User entered '15 Sep 2020 21:47'	System	16 Sep 2020 04:47:54

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 7'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:11:57', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '072e8394-8d95-49ed-b487-3b917f8db2a8'	System	17 Sep 2020 06:12:10
User entered 'Yes (Y)'	System	17 Sep 2020 06:12:10

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:02', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '072e8394-8d95-49ed-b487-3b917f8db2a8'	System	17 Sep 2020 06:12:10
User entered '98.4'	System	17 Sep 2020 06:12:10

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:04', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '072e8394-8d95-49ed-b487-3b917f8db2a8'	System	17 Sep 2020 06:12:10
User entered 'No (N)'	System	17 Sep 2020 06:12:10

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:07', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '072e8394-8d95-49ed-b487-3b917f8db2a8'	System	17 Sep 2020 06:12:10
User entered '16 Sep 2020 23:12'	System	17 Sep 2020 06:12:10

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3b5996f9-f39b-47b0-a9de-7d69c00e5b72'	System	10 Sep 2020 23:43:13
User entered 'None (1)'	System	10 Sep 2020 23:43:13

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:02', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3b5996f9-f39b-47b0-a9de-7d69c00e5b72'	System	10 Sep 2020 23:43:13
User entered 'No (N)'	System	10 Sep 2020 23:43:13

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:04', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3b5996f9-f39b-47b0-a9de-7d69c00e5b72'	System	10 Sep 2020 23:43:13
User entered 'No (N)'	System	10 Sep 2020 23:43:13

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:07', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3b5996f9-f39b-47b0-a9de-7d69c00e5b72'	System	10 Sep 2020 23:43:13
User entered 'None (1)'	System	10 Sep 2020 23:43:13

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:09', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3b5996f9-f39b-47b0-a9de-7d69c00e5b72'	System	10 Sep 2020 23:43:13
User entered '10 Sep 2020 16:43'	System	10 Sep 2020 23:43:13

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Sep 2020 16:35'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Sep 2020 19:05'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:37', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b3c2e36c-726c-4f31-9360-5f31c361fe06'	System	11 Sep 2020 03:00:48
User entered 'None (1)'	System	11 Sep 2020 03:00:48

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:39', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b3c2e36c-726c-4f31-9360-5f31c361fe06'	System	11 Sep 2020 03:00:48
User entered 'No (N)'	System	11 Sep 2020 03:00:48

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:41', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b3c2e36c-726c-4f31-9360-5f31c361fe06'	System	11 Sep 2020 03:00:48
User entered 'No (N)'	System	11 Sep 2020 03:00:48

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:43', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b3c2e36c-726c-4f31-9360-5f31c361fe06'	System	11 Sep 2020 03:00:48
User entered 'None (1)'	System	11 Sep 2020 03:00:48

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:45', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b3c2e36c-726c-4f31-9360-5f31c361fe06'	System	11 Sep 2020 03:00:48
User entered '10 Sep 2020 20:00'	System	11 Sep 2020 03:00:48

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Sep 2020 20:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 2'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:33:15', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b828d3a6-b248-427d-b222-98a0253351b1'	System	12 Sep 2020 01:33:54
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 01:33:54

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:33:38', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b828d3a6-b248-427d-b222-98a0253351b1'	System	12 Sep 2020 01:33:54
User entered 'No (N)'	System	12 Sep 2020 01:33:54

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:33:41', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b828d3a6-b248-427d-b222-98a0253351b1'	System	12 Sep 2020 01:33:54
User entered 'No (N)'	System	12 Sep 2020 01:33:54

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:33:46', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b828d3a6-b248-427d-b222-98a0253351b1'	System	12 Sep 2020 01:33:54
User entered 'None (1)'	System	12 Sep 2020 01:33:54

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:33:49', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b828d3a6-b248-427d-b222-98a0253351b1'	System	12 Sep 2020 01:33:54
User entered '11 Sep 2020 18:33'	System	12 Sep 2020 01:33:54

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 3'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:13', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c1e4877e-a0db-4d6f-a123-1bd3d16caadc'	System	12 Sep 2020 23:32:58
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 23:32:58

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:16', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c1e4877e-a0db-4d6f-a123-1bd3d16caadc'	System	12 Sep 2020 23:32:58
User entered 'No (N)'	System	12 Sep 2020 23:32:58

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:19', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c1e4877e-a0db-4d6f-a123-1bd3d16caadc'	System	12 Sep 2020 23:32:58
User entered 'No (N)'	System	12 Sep 2020 23:32:58

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:21', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c1e4877e-a0db-4d6f-a123-1bd3d16caadc'	System	12 Sep 2020 23:32:58
User entered 'None (1)'	System	12 Sep 2020 23:32:58

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:23', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c1e4877e-a0db-4d6f-a123-1bd3d16caadc'	System	12 Sep 2020 23:32:58
User entered '12 Sep 2020 16:32'	System	12 Sep 2020 23:32:58

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 4'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:21', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '9b6cce0b-b4a3-4146-95c2-7ef9d75e9c39'	System	14 Sep 2020 03:29:34
User entered 'None (1)'	System	14 Sep 2020 03:29:34

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:24', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '9b6cce0b-b4a3-4146-95c2-7ef9d75e9c39'	System	14 Sep 2020 03:29:34
User entered 'No (N)'	System	14 Sep 2020 03:29:34

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:27', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '9b6cce0b-b4a3-4146-95c2-7ef9d75e9c39'	System	14 Sep 2020 03:29:34
User entered 'No (N)'	System	14 Sep 2020 03:29:34

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:29', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '9b6cce0b-b4a3-4146-95c2-7ef9d75e9c39'	System	14 Sep 2020 03:29:34
User entered 'None (1)'	System	14 Sep 2020 03:29:34

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:32', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '9b6cce0b-b4a3-4146-95c2-7ef9d75e9c39'	System	14 Sep 2020 03:29:34
User entered '13 Sep 2020 20:29'	System	14 Sep 2020 03:29:34

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 5'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:03:57', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '57db3715-8914-4be1-a186-858e994a4322'	System	15 Sep 2020 06:04:13
User entered 'None (1)'	System	15 Sep 2020 06:04:13

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:01', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '57db3715-8914-4be1-a186-858e994a4322'	System	15 Sep 2020 06:04:13
User entered 'No (N)'	System	15 Sep 2020 06:04:13

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:03', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '57db3715-8914-4be1-a186-858e994a4322'	System	15 Sep 2020 06:04:13
User entered 'No (N)'	System	15 Sep 2020 06:04:13

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:05', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '57db3715-8914-4be1-a186-858e994a4322'	System	15 Sep 2020 06:04:13
User entered 'None (1)'	System	15 Sep 2020 06:04:13

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:07', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '57db3715-8914-4be1-a186-858e994a4322'	System	15 Sep 2020 06:04:13
User entered '14 Sep 2020 23:04'	System	15 Sep 2020 06:04:13

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 6'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:09', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6f3b427c-a8f1-4058-ae7b-9c93ce8899ce'	System	16 Sep 2020 04:48:21
User entered 'None (1)'	System	16 Sep 2020 04:48:21

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:11', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6f3b427c-a8f1-4058-ae7b-9c93ce8899ce'	System	16 Sep 2020 04:48:21
User entered 'No (N)'	System	16 Sep 2020 04:48:21

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:13', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6f3b427c-a8f1-4058-ae7b-9c93ce8899ce'	System	16 Sep 2020 04:48:21
User entered 'No (N)'	System	16 Sep 2020 04:48:21

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:14', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6f3b427c-a8f1-4058-ae7b-9c93ce8899ce'	System	16 Sep 2020 04:48:21
User entered 'None (1)'	System	16 Sep 2020 04:48:21

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:16', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6f3b427c-a8f1-4058-ae7b-9c93ce8899ce'	System	16 Sep 2020 04:48:21
User entered '15 Sep 2020 21:48'	System	16 Sep 2020 04:48:21

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 7'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:42', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6eafb768-887a-4e62-9b72-fa135324d612'	System	17 Sep 2020 06:12:53
User entered 'None (1)'	System	17 Sep 2020 06:12:53

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:44', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6eafb768-887a-4e62-9b72-fa135324d612'	System	17 Sep 2020 06:12:53
User entered 'No (N)'	System	17 Sep 2020 06:12:53

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:45', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6eafb768-887a-4e62-9b72-fa135324d612'	System	17 Sep 2020 06:12:53
User entered 'No (N)'	System	17 Sep 2020 06:12:53

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:47', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6eafb768-887a-4e62-9b72-fa135324d612'	System	17 Sep 2020 06:12:53
User entered 'None (1)'	System	17 Sep 2020 06:12:53

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:50', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '6eafb768-887a-4e62-9b72-fa135324d612'	System	17 Sep 2020 06:12:53
User entered '16 Sep 2020 23:12'	System	17 Sep 2020 06:12:53

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:13', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '465bb995-dd66-4479-be40-49bbc5d01bcc'	System	10 Sep 2020 23:43:27
User entered 'None (0)'	System	10 Sep 2020 23:43:27

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:14', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '465bb995-dd66-4479-be40-49bbc5d01bcc'	System	10 Sep 2020 23:43:27
User entered 'None (0)'	System	10 Sep 2020 23:43:27

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:16', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '465bb995-dd66-4479-be40-49bbc5d01bcc'	System	10 Sep 2020 23:43:27
User entered 'None (0)'	System	10 Sep 2020 23:43:27

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:17', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '465bb995-dd66-4479-be40-49bbc5d01bcc'	System	10 Sep 2020 23:43:27
User entered 'None (0)'	System	10 Sep 2020 23:43:27

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:18', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '465bb995-dd66-4479-be40-49bbc5d01bcc'	System	10 Sep 2020 23:43:27
User entered 'None (0)'	System	10 Sep 2020 23:43:27

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:20', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '465bb995-dd66-4479-be40-49bbc5d01bcc'	System	10 Sep 2020 23:43:27
User entered 'None (0)'	System	10 Sep 2020 23:43:27

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:22', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '465bb995-dd66-4479-be40-49bbc5d01bcc'	System	10 Sep 2020 23:43:27
User entered 'No (N)'	System	10 Sep 2020 23:43:27

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T16:43:24', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '465bb995-dd66-4479-be40-49bbc5d01bcc'	System	10 Sep 2020 23:43:27
User entered '10 Sep 2020 16:43'	System	10 Sep 2020 23:43:27

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Sep 2020 16:35'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Sep 2020 19:05'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:49', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78c6e024-3d5b-4a8a-9cd4-e698d1057de0'	System	11 Sep 2020 03:01:07
User entered 'None (0)'	System	11 Sep 2020 03:01:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:51', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78c6e024-3d5b-4a8a-9cd4-e698d1057de0'	System	11 Sep 2020 03:01:07
User entered 'None (0)'	System	11 Sep 2020 03:01:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:52', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78c6e024-3d5b-4a8a-9cd4-e698d1057de0'	System	11 Sep 2020 03:01:07
User entered 'None (0)'	System	11 Sep 2020 03:01:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:55', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78c6e024-3d5b-4a8a-9cd4-e698d1057de0'	System	11 Sep 2020 03:01:07
User entered 'None (0)'	System	11 Sep 2020 03:01:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78c6e024-3d5b-4a8a-9cd4-e698d1057de0'	System	11 Sep 2020 03:01:07
User entered 'None (0)'	System	11 Sep 2020 03:01:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:00:58', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78c6e024-3d5b-4a8a-9cd4-e698d1057de0'	System	11 Sep 2020 03:01:07
User entered 'None (0)'	System	11 Sep 2020 03:01:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:01:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78c6e024-3d5b-4a8a-9cd4-e698d1057de0'	System	11 Sep 2020 03:01:07
User entered 'No (N)'	System	11 Sep 2020 03:01:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-10T20:01:03', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78c6e024-3d5b-4a8a-9cd4-e698d1057de0'	System	11 Sep 2020 03:01:07
User entered '10 Sep 2020 20:01'	System	11 Sep 2020 03:01:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '10 Sep 2020 20:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 2'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:33:54', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '23fb1996-c174-4f9e-8aed-4aa3ec56bb1e'	System	12 Sep 2020 01:34:21
User entered 'None (0)'	System	12 Sep 2020 01:34:21

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:33:57', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '23fb1996-c174-4f9e-8aed-4aa3ec56bb1e'	System	12 Sep 2020 01:34:21
User entered 'None (0)'	System	12 Sep 2020 01:34:21

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:34:02', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '23fb1996-c174-4f9e-8aed-4aa3ec56bb1e'	System	12 Sep 2020 01:34:21
User entered 'None (0)'	System	12 Sep 2020 01:34:21

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:34:05', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '23fb1996-c174-4f9e-8aed-4aa3ec56bb1e'	System	12 Sep 2020 01:34:21
User entered 'None (0)'	System	12 Sep 2020 01:34:21

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:34:07', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '23fb1996-c174-4f9e-8aed-4aa3ec56bb1e'	System	12 Sep 2020 01:34:21
User entered 'None (0)'	System	12 Sep 2020 01:34:21

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:34:10', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '23fb1996-c174-4f9e-8aed-4aa3ec56bb1e'	System	12 Sep 2020 01:34:21
User entered 'None (0)'	System	12 Sep 2020 01:34:21

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:34:14', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '23fb1996-c174-4f9e-8aed-4aa3ec56bb1e'	System	12 Sep 2020 01:34:21
User entered 'No (N)'	System	12 Sep 2020 01:34:21

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-11T18:34:17', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '23fb1996-c174-4f9e-8aed-4aa3ec56bb1e'	System	12 Sep 2020 01:34:21
User entered '11 Sep 2020 18:34'	System	12 Sep 2020 01:34:21

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 3'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:27', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5fc43a90-1e10-49e9-acc6-15484b4f7bf2'	System	12 Sep 2020 23:33:13
User entered 'None (0)'	System	12 Sep 2020 23:33:13

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:29', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5fc43a90-1e10-49e9-acc6-15484b4f7bf2'	System	12 Sep 2020 23:33:13
User entered 'None (0)'	System	12 Sep 2020 23:33:13

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:32', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5fc43a90-1e10-49e9-acc6-15484b4f7bf2'	System	12 Sep 2020 23:33:13
User entered 'None (0)'	System	12 Sep 2020 23:33:13

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:36', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5fc43a90-1e10-49e9-acc6-15484b4f7bf2'	System	12 Sep 2020 23:33:13
User entered 'None (0)'	System	12 Sep 2020 23:33:13

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:38', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5fc43a90-1e10-49e9-acc6-15484b4f7bf2'	System	12 Sep 2020 23:33:13
User entered 'None (0)'	System	12 Sep 2020 23:33:13

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:39', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5fc43a90-1e10-49e9-acc6-15484b4f7bf2'	System	12 Sep 2020 23:33:13
User entered 'None (0)'	System	12 Sep 2020 23:33:13

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:42', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5fc43a90-1e10-49e9-acc6-15484b4f7bf2'	System	12 Sep 2020 23:33:13
User entered 'No (N)'	System	12 Sep 2020 23:33:13

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-12T16:32:44', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '5fc43a90-1e10-49e9-acc6-15484b4f7bf2'	System	12 Sep 2020 23:33:13
User entered '12 Sep 2020 16:32'	System	12 Sep 2020 23:33:13

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 4'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:37', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1eaca1d-3e40-4b9e-9a3d-b324134a44b6'	System	14 Sep 2020 03:29:55
User entered 'None (0)'	System	14 Sep 2020 03:29:55

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:39', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1eaca1d-3e40-4b9e-9a3d-b324134a44b6'	System	14 Sep 2020 03:29:55
User entered 'None (0)'	System	14 Sep 2020 03:29:55

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:41', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1eaca1d-3e40-4b9e-9a3d-b324134a44b6'	System	14 Sep 2020 03:29:55
User entered 'None (0)'	System	14 Sep 2020 03:29:55

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:44', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1eaca1d-3e40-4b9e-9a3d-b324134a44b6'	System	14 Sep 2020 03:29:55
User entered 'None (0)'	System	14 Sep 2020 03:29:55

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:45', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1eaca1d-3e40-4b9e-9a3d-b324134a44b6'	System	14 Sep 2020 03:29:55
User entered 'None (0)'	System	14 Sep 2020 03:29:55

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:47', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1eaca1d-3e40-4b9e-9a3d-b324134a44b6'	System	14 Sep 2020 03:29:55
User entered 'None (0)'	System	14 Sep 2020 03:29:55

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:50', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1eaca1d-3e40-4b9e-9a3d-b324134a44b6'	System	14 Sep 2020 03:29:55
User entered 'No (N)'	System	14 Sep 2020 03:29:55

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-13T20:29:52', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1eaca1d-3e40-4b9e-9a3d-b324134a44b6'	System	14 Sep 2020 03:29:55
User entered '13 Sep 2020 20:29'	System	14 Sep 2020 03:29:55

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 5'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:11', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '89eade83-de05-469d-b0d6-94297894657b'	System	15 Sep 2020 06:04:29
User entered 'None (0)'	System	15 Sep 2020 06:04:29

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:13', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '89eade83-de05-469d-b0d6-94297894657b'	System	15 Sep 2020 06:04:29
User entered 'None (0)'	System	15 Sep 2020 06:04:29

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:15', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '89eade83-de05-469d-b0d6-94297894657b'	System	15 Sep 2020 06:04:29
User entered 'None (0)'	System	15 Sep 2020 06:04:29

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:17', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '89eade83-de05-469d-b0d6-94297894657b'	System	15 Sep 2020 06:04:29
User entered 'None (0)'	System	15 Sep 2020 06:04:29

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:18', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '89eade83-de05-469d-b0d6-94297894657b'	System	15 Sep 2020 06:04:29
User entered 'None (0)'	System	15 Sep 2020 06:04:29

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:20', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '89eade83-de05-469d-b0d6-94297894657b'	System	15 Sep 2020 06:04:29
User entered 'None (0)'	System	15 Sep 2020 06:04:29

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:22', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '89eade83-de05-469d-b0d6-94297894657b'	System	15 Sep 2020 06:04:29
User entered 'No (N)'	System	15 Sep 2020 06:04:29

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-14T23:04:24', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '89eade83-de05-469d-b0d6-94297894657b'	System	15 Sep 2020 06:04:29
User entered '14 Sep 2020 23:04'	System	15 Sep 2020 06:04:29

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 6'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:20', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '48c8f2f7-f457-45fd-991e-2da2e47c127b'	System	16 Sep 2020 04:48:41
User entered 'None (0)'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:22', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '48c8f2f7-f457-45fd-991e-2da2e47c127b'	System	16 Sep 2020 04:48:41
User entered 'None (0)'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:24', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '48c8f2f7-f457-45fd-991e-2da2e47c127b'	System	16 Sep 2020 04:48:41
User entered 'None (0)'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:26', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '48c8f2f7-f457-45fd-991e-2da2e47c127b'	System	16 Sep 2020 04:48:41
User entered 'None (0)'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:31', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '48c8f2f7-f457-45fd-991e-2da2e47c127b'	System	16 Sep 2020 04:48:41
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:33', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '48c8f2f7-f457-45fd-991e-2da2e47c127b'	System	16 Sep 2020 04:48:41
User entered 'None (0)'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:37', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '48c8f2f7-f457-45fd-991e-2da2e47c127b'	System	16 Sep 2020 04:48:41
User entered 'No (N)'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-15T21:48:39', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '48c8f2f7-f457-45fd-991e-2da2e47c127b'	System	16 Sep 2020 04:48:41
User entered '15 Sep 2020 21:48'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	10 Sep 2020 23:16:07
User entered 'Day 7'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:54', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'd690106a-b654-42f4-90b4-938da9d5fb1d'	System	17 Sep 2020 06:13:15
User entered 'None (0)'	System	17 Sep 2020 06:13:15

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'd690106a-b654-42f4-90b4-938da9d5fb1d'	System	17 Sep 2020 06:13:15
User entered 'None (0)'	System	17 Sep 2020 06:13:15

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:12:58', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'd690106a-b654-42f4-90b4-938da9d5fb1d'	System	17 Sep 2020 06:13:15
User entered 'None (0)'	System	17 Sep 2020 06:13:15

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:13:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'd690106a-b654-42f4-90b4-938da9d5fb1d'	System	17 Sep 2020 06:13:15
User entered 'None (0)'	System	17 Sep 2020 06:13:15

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:13:04', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'd690106a-b654-42f4-90b4-938da9d5fb1d'	System	17 Sep 2020 06:13:15
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	17 Sep 2020 06:13:15

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:13:06', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'd690106a-b654-42f4-90b4-938da9d5fb1d'	System	17 Sep 2020 06:13:15
User entered 'None (0)'	System	17 Sep 2020 06:13:15

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:13:09', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'd690106a-b654-42f4-90b4-938da9d5fb1d'	System	17 Sep 2020 06:13:15
User entered 'Yes (Y)'	System	17 Sep 2020 06:13:15

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-16T23:13:11', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'd690106a-b654-42f4-90b4-938da9d5fb1d'	System	17 Sep 2020 06:13:15
User entered '16 Sep 2020 23:13'	System	17 Sep 2020 06:13:15

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 23:16:07

US3462101

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	16 Sep 2020 04:48:41
User entered 'Day 8'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:39:54

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-17T21:10:18', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'ad2f8eb8-049b-47c8-96c5-b625167dcf1e'	System	18 Sep 2020 04:10:24
User entered 'None (0)'	System	18 Sep 2020 04:10:24

US3462101

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-17T21:10:21', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'ad2f8eb8-049b-47c8-96c5-b625167dcf1e'	System	18 Sep 2020 04:10:24
User entered '17 Sep 2020 21:10'	System	18 Sep 2020 04:10:24

US3462101

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	16 Sep 2020 04:48:41
User entered 'Day 8'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-17T21:10:24', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f23030ad-bb16-4e90-9fb9-83943d86ca50'	System	18 Sep 2020 04:10:30
User entered 'No (N)'	System	18 Sep 2020 04:10:30

US3462101

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-09-17T21:10:27', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f23030ad-bb16-4e90-9fb9-83943d86ca50'	System	18 Sep 2020 04:10:30
User entered '17 Sep 2020 21:10'	System	18 Sep 2020 04:10:30

US3462101

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 04:48:41

US3462101

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:39:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 04:48:41

US3462101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:48:41
User entered 'Yes (Y)'		05 Oct 2020 19:23:30

US3462101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:48:41
User entered '17 Sep 2020'		05 Oct 2020 19:23:30

US3462101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:48:41
User entered 'Contact Made (CONTACT MADE)'		05 Oct 2020 19:23:30

US3462101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:48:41
User entered empty.		05 Oct 2020 19:23:30

US3462101

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:48:49
User entered 'Yes (Y)'		05 Oct 2020 19:24:06

US3462101

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'I'	System	05 Oct 2020 19:24:06

US3462101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:49:06
User entered 'Yes (Y)'		05 Oct 2020 19:24:45

US3462101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:49:06
User entered '24 Sep 2020'		05 Oct 2020 19:24:45

US3462101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:49:06
User entered 'Contact Made (CONTACT MADE)'		05 Oct 2020 19:24:45

US3462101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:49:06
User entered empty.		05 Oct 2020 19:24:45

US3462101

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:52:24
User entered 'Yes (Y)'		05 Oct 2020 19:27:45

US3462101

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'I'	System	05 Oct 2020 19:27:45

US3462101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:54:35
Comment added 'SAFETY CALL #3 WAS FIRST ATTEMPTED ON 10/01/2020, THEN ON THE 10/05/2020.FINALLY SUBJECT RETURNED CALL ON 10/06/2020'.		21 Oct 2020 21:53:17
User entered 'Yes (Y)'		05 Oct 2020 19:28:11

US3462101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:54:35
User closed query 'Per CDM: 'Date of Contact or Contact Attempt' is greater than 24days after Visit 2 treatment date. Please review and update as appropriate else confirm the date is correct in query response. Thank you' (Site from DM).		29 Oct 2020 14:03:52
Query 'Per CDM: 'Date of Contact or Contact Attempt' is greater than 24days after Visit 2 treatment date. Please review and update as appropriate else confirm the date is correct in query response. Thank you' answered with 'SAFETY CALL#3 WAS ATTEMPTED ON 10/01/2020 WITH NO RESPONSE,ATTEMPTED AGAIN ON 10/05/2020. FINALLY SUBJECT RETURNED CALL ON 10/06/20. ALL ATTEMPTS DOCUMENTED IN SOURCE. ALL NECESSARY DATA ENTRY WILL BE UPDATED' (Site from DM).		21 Oct 2020 21:50:28
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		21 Oct 2020 05:52:15
User opened query 'Per CDM: 'Date of Contact or Contact Attempt' is greater than 24days after Visit 2 treatment date. Please review and update as appropriate else confirm the date is correct in query response. Thank you' (Site from DM).		21 Oct 2020 05:52:13
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data entry error. ' (Site from System).		08 Oct 2020 00:24:58
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Oct 2020 00:23:06

US3462101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 00:23:06
User entered '01 Oct 2020'		05 Oct 2020 19:28:11

US3462101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:54:35
Comment added 'contact was made on the 6th october'.		08 Oct 2020 00:24:54
User entered 'Contact Made (CONTACT MADE)'		05 Oct 2020 19:28:11

US3462101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:54:35
Comment added 'SAFETY CALL#3 WAS ATTEMPTED ON 10/01/2020 BUT FINALLY GOT HOLD OF SUBJECT ON 10/06/2020'.		21 Oct 2020 21:55:12
User entered empty.		05 Oct 2020 19:28:11

US3462101

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:55:12
User entered 'Yes (Y)'		05 Oct 2020 19:28:19

US3462101

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'I'	System	05 Oct 2020 19:28:19

US3462101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:00:37
User entered 'Yes (Y)'		07 Oct 2020 23:16:41

US3462101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:00:37
User entered '07 Oct 2020'		07 Oct 2020 23:16:41

US3462101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[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 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:00:37
User entered 'Clinic (Clinic)'		07 Oct 2020 23:16:41

US3462101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User entered 'VISIT3'	System	07 Oct 2020 23:16:41

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:46
User entered 'No (N)'		19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	06 Nov 2020 00:12:46
User entered empty.		19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:46
User entered empty.		19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User entered empty.	System	19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:46
User entered empty.		19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:46
User entered empty.		19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:46
User entered empty.		19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:46
User entered empty.		19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User entered empty.	System	19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:46
User entered empty.		19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User entered empty.	System	19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:46
User entered empty.		19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User entered empty.	System	19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:46
User entered empty.		19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56
User entered empty.	System	19 Oct 2020 21:22:18

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56

US3462101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:56

US3462101

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:50
User entered 'No (N)'		19 Oct 2020 21:22:24

US3462101

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:12:50
User entered empty.		19 Oct 2020 21:22:24

US3462101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:14:40
User entered 'Yes (Y)'		19 Oct 2020 21:22:41

US3462101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:14:40
User entered '07 Oct 2020'		19 Oct 2020 21:22:41

US3462101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:14:40
User entered '15:35'		19 Oct 2020 21:22:41

US3462101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered '07 Oct 2020 15:35'	System	19 Oct 2020 21:22:41

US3462101

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:23:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:14:46
User entered 'Yes (Y)'		19 Oct 2020 21:22:46

US3462101

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'I'	System	19 Oct 2020 21:22:46

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 64'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-10-12T23:38:28', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '75d86bb5-66ca-433f-8a2b-855df4525642'	System	13 Oct 2020 06:38:50
User entered 'No (N)'	System	13 Oct 2020 06:38:50

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-10-12T23:38:31', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '75d86bb5-66ca-433f-8a2b-855df4525642'	System	13 Oct 2020 06:38:50
User entered 'No (N)'	System	13 Oct 2020 06:38:50

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-10-12T23:38:34', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '75d86bb5-66ca-433f-8a2b-855df4525642'	System	13 Oct 2020 06:38:50
User entered '12 Oct 2020 23:38:34'	System	13 Oct 2020 06:38:50

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered '10 Oct 2020 00:01'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered '14 Oct 2020 23:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 71'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-10-18T02:40:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'ccb1780f-2d34-4dc0-a5a3-25f299f10894'	System	18 Oct 2020 09:40:11
User entered 'No (N)'	System	18 Oct 2020 09:40:11

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-10-18T02:40:03', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'ccb1780f-2d34-4dc0-a5a3-25f299f10894'	System	18 Oct 2020 09:40:11
User entered 'No (N)'	System	18 Oct 2020 09:40:11

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-10-18T02:40:05', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'ccb1780f-2d34-4dc0-a5a3-25f299f10894'	System	18 Oct 2020 09:40:11
User entered '18 Oct 2020 02:40:05'	System	18 Oct 2020 09:40:11

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered '17 Oct 2020 00:01'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered '21 Oct 2020 23:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 78'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-10-24T06:51:14', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e3e64414-73c0-4aaa-b73d-b54efc838c35'	System	24 Oct 2020 13:51:26
User entered 'No (N)'	System	24 Oct 2020 13:51:26

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-10-24T06:51:17', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e3e64414-73c0-4aaa-b73d-b54efc838c35'	System	24 Oct 2020 13:51:26
User entered 'No (N)'	System	24 Oct 2020 13:51:26

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-10-24T06:51:20', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e3e64414-73c0-4aaa-b73d-b54efc838c35'	System	24 Oct 2020 13:51:26
User entered '24 Oct 2020 06:51:20'	System	24 Oct 2020 13:51:26

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered '24 Oct 2020 00:01'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered '28 Oct 2020 23:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 92'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-11-07T00:11:28', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c49adc57-08ef-4a84-8cb6-d4e9e51263f9'	System	07 Nov 2020 08:11:39
User entered 'No (N)'	System	07 Nov 2020 08:11:39

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-11-07T00:11:31', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c49adc57-08ef-4a84-8cb6-d4e9e51263f9'	System	07 Nov 2020 08:11:39
User entered 'No (N)'	System	07 Nov 2020 08:11:39

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74a5b716d0a76669)', Time: '2020-11-07T00:11:33', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'c49adc57-08ef-4a84-8cb6-d4e9e51263f9'	System	07 Nov 2020 08:11:39
User entered '07 Nov 2020 00:11:33'	System	07 Nov 2020 08:11:39

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered '07 Nov 2020 00:01'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:24:22
Data entry locked.	System	11 Aug 2020 00:12:20
User entered '11 Nov 2020 23:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51
Data entry locked.	System	11 Aug 2020 00:12:20
User entered 'Day 99'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51
Data entry locked.	System	11 Aug 2020 00:12:20
User entered '14 Nov 2020 00:01'	System	11 Aug 2020 00:12:20

US3462101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:21:51
Data entry locked.	System	11 Aug 2020 00:12:20
User entered '18 Nov 2020 23:59'	System	11 Aug 2020 00:12:20

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2020-11-19T16:45:38', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3fedd53c-9e82-43ac-8c7e-9a6f4623bd21'	System	20 Nov 2020 00:45:46
User entered 'No (N)'	System	20 Nov 2020 00:45:46

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2020-11-19T16:45:41', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3fedd53c-9e82-43ac-8c7e-9a6f4623bd21'	System	20 Nov 2020 00:45:46
User entered 'No (N)'	System	20 Nov 2020 00:45:46

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2020-11-19T16:45:44', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3fedd53c-9e82-43ac-8c7e-9a6f4623bd21'	System	20 Nov 2020 00:45:46
User entered '19 Nov 2020 16:45:44'	System	20 Nov 2020 00:45:46

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2020-11-25T02:57:41', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '56e4a193-dead-4089-a790-9ca2a7449e64'	System	25 Nov 2020 10:57:51
User entered 'No (N)'	System	25 Nov 2020 10:57:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2020-11-25T02:57:44', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '56e4a193-dead-4089-a790-9ca2a7449e64'	System	25 Nov 2020 10:57:51
User entered 'No (N)'	System	25 Nov 2020 10:57:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2020-11-25T02:57:47', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '56e4a193-dead-4089-a790-9ca2a7449e64' User entered '25 Nov 2020 02:57:47'	System	25 Nov 2020 10:57:51
	System	25 Nov 2020 10:57:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2020-12-02T03:57:22', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '30e09721-6cbc-4ae3-93c1-388e698dd516'	System	02 Dec 2020 11:57:42
User entered 'No (N)'	System	02 Dec 2020 11:57:42

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2020-12-02T03:57:36', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '30e09721-6cbc-4ae3-93c1-388e698dd516'	System	02 Dec 2020 11:57:42
User entered 'No (N)'	System	02 Dec 2020 11:57:42

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2020-12-02T03:57:38', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '30e09721-6cbc-4ae3-93c1-388e698dd516'	System	02 Dec 2020 11:57:42
User entered '02 Dec 2020 03:57:38'	System	02 Dec 2020 11:57:42

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2020-12-09T18:33:35', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '02b608e8-9f96-464e-878e-63d155536e47'	System	10 Dec 2020 02:33:55
User entered 'No (N)'	System	10 Dec 2020 02:33:55

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2020-12-09T18:33:37', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '02b608e8-9f96-464e-878e-63d155536e47'	System	10 Dec 2020 02:33:55
User entered 'Yes (Y)'	System	10 Dec 2020 02:33:55

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Please 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 (bf701a8ae159b8a0)', Time: '2020-12-09T18:33:43', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '02b608e8-9f96-464e-878e-63d155536e47'	System	10 Dec 2020 02:33:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Dec 2020 02:33:55

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2020-12-09T18:33:46', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '02b608e8-9f96-464e-878e-63d155536e47'	System	10 Dec 2020 02:33:55
User entered '09 Dec 2020 18:33:46'	System	10 Dec 2020 02:33:55

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2020-12-16T09:14:26', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '8c02d6fb-ce05-4ff6-aec1-ab0d1e36648f'	System	16 Dec 2020 17:14:53
User entered 'No (N)'	System	16 Dec 2020 17:14:53

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2020-12-16T09:14:34', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '8c02d6fb-ce05-4ff6-aec1-ab0d1e36648f'	System	16 Dec 2020 17:14:53
User entered 'No (N)'	System	16 Dec 2020 17:14:53

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2020-12-16T09:14:51', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '8c02d6fb-ce05-4ff6-aec1-ab0d1e36648f' User entered '16 Dec 2020 09:14:51'	System	16 Dec 2020 17:14:53
	System	16 Dec 2020 17:14:53

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2020-12-23T00:34:40', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '11ca2007-93b4-4341-bf40-b48e653c385f'	System	23 Dec 2020 08:34:48
User entered 'No (N)'	System	23 Dec 2020 08:34:48

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2020-12-23T00:34:42', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '11ca2007-93b4-4341-bf40-b48e653c385f'	System	23 Dec 2020 08:34:48
User entered 'No (N)'	System	23 Dec 2020 08:34:48

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2020-12-23T00:34:46', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '11ca2007-93b4-4341-bf40-b48e653c385f' User entered '23 Dec 2020 00:34:46'	System	23 Dec 2020 08:34:48
	System	23 Dec 2020 08:34:48

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2020-12-30T05:12:32', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'bb810c2e-31c0-460d-a5ff-1bf588b799fe'	System	30 Dec 2020 13:12:42
User entered 'No (N)'	System	30 Dec 2020 13:12:42

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2020-12-30T05:12:36', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'bb810c2e-31c0-460d-a5ff-1bf588b799fe'	System	30 Dec 2020 13:12:42
User entered 'No (N)'	System	30 Dec 2020 13:12:42

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2020-12-30T05:12:39', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'bb810c2e-31c0-460d-a5ff-1bf588b799fe' User entered '30 Dec 2020 05:12:39'	System	30 Dec 2020 13:12:42
	System	30 Dec 2020 13:12:42

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-01-10T01:03:25', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '1a2f94fe-71f4-412f-864d-c92bd130a91b'	System	10 Jan 2021 09:04:03
User entered 'Yes (Y)'	System	10 Jan 2021 09:04:03

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-01-10T01:03:28', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '1a2f94fe-71f4-412f-864d-c92bd130a91b'	System	10 Jan 2021 09:04:03
User entered 'No (N)'	System	10 Jan 2021 09:04:03

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-01-10T01:03:34', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '1a2f94fe-71f4-412f-864d-c92bd130a91b'	System	10 Jan 2021 09:04:03
User entered 'No (N)'	System	10 Jan 2021 09:04:03

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-01-10T01:03:38', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '1a2f94fe-71f4-412f-864d-c92bd130a91b'	System	10 Jan 2021 09:04:03
User entered 'Yes (Y)'	System	10 Jan 2021 09:04:03

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Please 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 (bf701a8ae159b8a0)', Time: '2021-01-10T01:03:43', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '1a2f94fe-71f4-412f-864d-c92bd130a91b'	System	10 Jan 2021 09:04:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 09:04:03

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-01-10T01:03:52', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '1a2f94fe-71f4-412f-864d-c92bd130a91b' User entered '10 Jan 2021 01:03:52'	System	10 Jan 2021 09:04:03
	System	10 Jan 2021 09:04:03

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-01-13T00:01:21', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a1bafa03-c9d4-4e9a-aed1-9c3e8256fc51'	System	13 Jan 2021 08:01:31
User entered 'No (N)'	System	13 Jan 2021 08:01:31

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-01-13T00:01:23', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a1bafa03-c9d4-4e9a-aed1-9c3e8256fc51'	System	13 Jan 2021 08:01:31
User entered 'No (N)'	System	13 Jan 2021 08:01:31

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-01-13T00:01:26', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a1bafa03-c9d4-4e9a-aed1-9c3e8256fc51' User entered '13 Jan 2021 00:01:26'	System	13 Jan 2021 08:01:31

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-01-20T12:35:53', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '9042388c-80ce-49bd-b6e3-8aaeb72fca29'	System	20 Jan 2021 20:36:04
User entered 'No (N)'	System	20 Jan 2021 20:36:04

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-01-20T12:35:57', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '9042388c-80ce-49bd-b6e3-8aaeb72fca29'	System	20 Jan 2021 20:36:04
User entered 'No (N)'	System	20 Jan 2021 20:36:04

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-01-20T12:35:59', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '9042388c-80ce-49bd-b6e3-8aaeb72fca29'	System	20 Jan 2021 20:36:04
User entered '20 Jan 2021 12:35:59'	System	20 Jan 2021 20:36:04

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-01-27T13:39:53', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a64b9ab2-2c0c-41ad-8f3b-e55aaf2672b5'	System	27 Jan 2021 21:40:04
User entered 'No (N)'	System	27 Jan 2021 21:40:04

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-01-27T13:39:56', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a64b9ab2-2c0c-41ad-8f3b-e55aaf2672b5'	System	27 Jan 2021 21:40:04
User entered 'No (N)'	System	27 Jan 2021 21:40:04

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-01-27T13:39:58', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a64b9ab2-2c0c-41ad-8f3b-e55aaf2672b5' User entered '27 Jan 2021 13:39:58'	System	27 Jan 2021 21:40:04

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-02-03T00:23:20', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'fa30ac2c-85e4-4c4a-b94a-57960935e3a2'	System	03 Feb 2021 08:23:28
User entered 'No (N)'	System	03 Feb 2021 08:23:28

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-02-03T00:23:22', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'fa30ac2c-85e4-4c4a-b94a-57960935e3a2'	System	03 Feb 2021 08:23:28
User entered 'No (N)'	System	03 Feb 2021 08:23:28

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-02-03T00:23:24', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'fa30ac2c-85e4-4c4a-b94a-57960935e3a2'	System	03 Feb 2021 08:23:28
User entered '03 Feb 2021 00:23:24'	System	03 Feb 2021 08:23:28

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-02-10T07:09:30', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7dc9a57d-a2e8-411b-94f2-adc1e2c88a03'	System	10 Feb 2021 15:09:38
User entered 'No (N)'	System	10 Feb 2021 15:09:38

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-02-10T07:09:33', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7dc9a57d-a2e8-411b-94f2-adc1e2c88a03'	System	10 Feb 2021 15:09:38
User entered 'No (N)'	System	10 Feb 2021 15:09:38

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-02-10T07:09:35', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7dc9a57d-a2e8-411b-94f2-adc1e2c88a03'	System	10 Feb 2021 15:09:38
User entered '10 Feb 2021 07:09:35'	System	10 Feb 2021 15:09:38

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-02-18T21:25:05', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '13086652-b13a-45b2-bccb-8a55181d0627'	System	19 Feb 2021 05:25:13
User entered 'No (N)'	System	19 Feb 2021 05:25:13

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-02-18T21:25:07', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '13086652-b13a-45b2-bccb-8a55181d0627'	System	19 Feb 2021 05:25:13
User entered 'No (N)'	System	19 Feb 2021 05:25:13

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-02-18T21:25:10', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '13086652-b13a-45b2-bccb-8a55181d0627'	System	19 Feb 2021 05:25:13
User entered '18 Feb 2021 21:25:10'	System	19 Feb 2021 05:25:13

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-02-24T09:40:41-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3a0558ef-b448-4d9c-9712-07e22b4efece' User entered 'No (N)'	System	24 Feb 2021 17:40:50
	System	24 Feb 2021 17:40:50

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-02-24T09:40:44-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3a0558ef-b448-4d9c-9712-07e22b4efece'	System	24 Feb 2021 17:40:50
User entered 'No (N)'	System	24 Feb 2021 17:40:50

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-02-24T09:40:47-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '3a0558ef-b448-4d9c-9712-07e22b4efece'	System	24 Feb 2021 17:40:50
User entered '24 Feb 2021 09:40:47'	System	24 Feb 2021 17:40:50

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-03-03T11:01:01-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f9170dfc-1123-457b-bfd6-1b84a4dd8c5c'	System	03 Mar 2021 19:01:13
User entered 'No (N)'	System	03 Mar 2021 19:01:13

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-03-03T11:01:03-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f9170dfc-1123-457b-bfd6-1b84a4dd8c5c'	System	03 Mar 2021 19:01:13
User entered 'No (N)'	System	03 Mar 2021 19:01:13

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-03-03T11:01:10-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f9170dfc-1123-457b-bfd6-1b84a4dd8c5c'	System	03 Mar 2021 19:01:13
User entered '03 Mar 2021 11:01:10'	System	03 Mar 2021 19:01:13

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-03-10T13:34:44-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1796b80-101a-4b68-b14a-c8ba95ca6db6' User entered 'No (N)'	System	10 Mar 2021 21:34:54
	System	10 Mar 2021 21:34:54

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-03-10T13:34:47-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1796b80-101a-4b68-b14a-c8ba95ca6db6'	System	10 Mar 2021 21:34:54
User entered 'No (N)'	System	10 Mar 2021 21:34:54

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-03-10T13:34:49-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'f1796b80-101a-4b68-b14a-c8ba95ca6db6' User entered '10 Mar 2021 13:34:49'	System	10 Mar 2021 21:34:54
	System	10 Mar 2021 21:34:54

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-03-17T11:02:08-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b0bc217d-4e89-48d8-9015-63b0f6dfdd6b' User entered 'No (N)'	System	17 Mar 2021 18:02:20
	System	17 Mar 2021 18:02:20

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-03-17T11:02:11-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b0bc217d-4e89-48d8-9015-63b0f6dfdd6b'	System	17 Mar 2021 18:02:20
User entered 'No (N)'	System	17 Mar 2021 18:02:20

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-03-17T11:02:14-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'b0bc217d-4e89-48d8-9015-63b0f6dfdd6b' User entered '17 Mar 2021 11:02:14'	System	17 Mar 2021 18:02:20
	System	17 Mar 2021 18:02:20

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-03-24T00:37:44-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e6ad9971-fa24-4048-95a6-0d44be856ff0'	System	24 Mar 2021 07:37:52
User entered 'No (N)'	System	24 Mar 2021 07:37:52

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-03-24T00:37:47-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e6ad9971-fa24-4048-95a6-0d44be856ff0'	System	24 Mar 2021 07:37:52
User entered 'No (N)'	System	24 Mar 2021 07:37:52

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-03-24T00:37:49-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e6ad9971-fa24-4048-95a6-0d44be856ff0'	System	24 Mar 2021 07:37:52
User entered '24 Mar 2021 00:37:49'	System	24 Mar 2021 07:37:52

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-03-31T00:15:45-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7696ff2e-afbc-4016-9d0b-6b4e56a4d6c4'	System	31 Mar 2021 07:15:53
User entered 'No (N)'	System	31 Mar 2021 07:15:53

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-03-31T00:15:47-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7696ff2e-afbc-4016-9d0b-6b4e56a4d6c4'	System	31 Mar 2021 07:15:53
User entered 'No (N)'	System	31 Mar 2021 07:15:53

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-03-31T00:15:50-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '7696ff2e-afbc-4016-9d0b-6b4e56a4d6c4'	System	31 Mar 2021 07:15:53
User entered '31 Mar 2021 00:15:50'	System	31 Mar 2021 07:15:53

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-04-07T23:29:06-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78d68ea4-6326-4216-ba9c-8e284e673168'	System	08 Apr 2021 06:29:13
User entered 'No (N)'	System	08 Apr 2021 06:29:13

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-04-07T23:29:08-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78d68ea4-6326-4216-ba9c-8e284e673168'	System	08 Apr 2021 06:29:13
User entered 'No (N)'	System	08 Apr 2021 06:29:13

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-04-07T23:29:10-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '78d68ea4-6326-4216-ba9c-8e284e673168'	System	08 Apr 2021 06:29:13
User entered '07 Apr 2021 23:29:10'	System	08 Apr 2021 06:29:13

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-04-14T08:32:00-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a176ffe0-bde6-484e-9c15-033c95e86d78'	System	14 Apr 2021 15:32:19
User entered 'No (N)'	System	14 Apr 2021 15:32:19

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-04-14T08:32:07-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a176ffe0-bde6-484e-9c15-033c95e86d78'	System	14 Apr 2021 15:32:19
User entered 'No (N)'	System	14 Apr 2021 15:32:19

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-04-14T08:32:10-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'a176ffe0-bde6-484e-9c15-033c95e86d78'	System	14 Apr 2021 15:32:19
User entered '14 Apr 2021 08:32:10'	System	14 Apr 2021 15:32:19

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-04-21T03:29:36-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e1372239-1f4f-4e02-96ef-2d7a2518bc9f' User entered 'No (N)'	System	21 Apr 2021 10:29:46
	System	21 Apr 2021 10:29:46

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-04-21T03:29:39-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e1372239-1f4f-4e02-96ef-2d7a2518bc9f'	System	21 Apr 2021 10:29:46
User entered 'No (N)'	System	21 Apr 2021 10:29:46

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-04-21T03:29:44-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e1372239-1f4f-4e02-96ef-2d7a2518bc9f' User entered '21 Apr 2021 03:29:44'	System	21 Apr 2021 10:29:46
	System	21 Apr 2021 10:29:46

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[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 (bf701a8ae159b8a0)', Time: '2021-04-28T01:04:57-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '95f78a9d-623e-467f-a3b0-dccf3060771f' User entered 'No (N)'	System	29 Apr 2021 00:58:30
	System	29 Apr 2021 00:58:30

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

Have you been exposed to someone with 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 (bf701a8ae159b8a0)', Time: '2021-04-28T01:05:00-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '95f78a9d-623e-467f-a3b0-dccf3060771f' User entered 'No (N)'	System	29 Apr 2021 00:58:30

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-04-28T01:05:02-07:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: '95f78a9d-623e-467f-a3b0-dccf3060771f' User entered '28 Apr 2021 01:05:02'	System	29 Apr 2021 00:58:30
	System	29 Apr 2021 00:58:30

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:21:51

US3462101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:39:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:21:51
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:21:51

US3462101

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:39:54

[Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-02-28T21:48:15-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e51fea78-f6b2-4f02-a182-9ad99fabcd1dd'	System	01 Mar 2021 05:48:21
User entered 'No (N)'	System	01 Mar 2021 05:48:21

US3462101

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:39:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:42:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bf701a8ae159b8a0)', Time: '2021-02-28T21:48:18-08:00', User OID: 'PatientReportedOutcome (US3462101)', ODM File OID: 'e51fea78-f6b2-4f02-a182-9ad99fabcd1dd'	System	01 Mar 2021 05:48:21
User entered '28 Feb 2021 21:48:18'	System	01 Mar 2021 05:48:21

US3462101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
DataPoint Verified.		07 Apr 2021 23:08:54
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:03:31

US3462101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
DataPoint Verified.		07 Apr 2021 23:08:54
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:03:31

US3462101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
DataPoint Verified.		07 Apr 2021 23:08:54
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:03:31

US3462101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
DataPoint Verified.		07 Apr 2021 23:08:54
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:03:31

US3462101

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
DataPoint Verified.		07 Apr 2021 23:09:11
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:03:38

US3462101

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:54
User entered 'I'	System	12 Nov 2020 21:03:38

US3462101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:09:44
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	06 Apr 2021 18:04:58
User entered 'Yes (Y)'	System	25 Mar 2021 17:08:34
	(b) (4), (b) (6)	25 Mar 2021 17:08:34

US3462101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:09:44
Signature has been broken.		07 Apr 2021 20:23:11
User entered '09 Dec 2020' reason for change: Data Entry Error		07 Apr 2021 20:23:11
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User entered '05 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:58
User entered empty.		25 Mar 2021 17:08:34

US3462101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:09:44
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 18:04:58
User entered empty.		25 Mar 2021 17:08:34

US3462101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:09:44
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:08:34

US3462101

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:09:50
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:08:41

US3462101

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
User entered 'I'	System	25 Mar 2021 17:08:41

US3462101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:14:04
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	06 Apr 2021 18:13:10
User entered 'Yes (Y)'	System	25 Mar 2021 17:08:47
	(b) (4), (b) (6)	25 Mar 2021 17:08:47

US3462101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
User signature succeeded.	Gregg Lucksinger (b) (4)	21 Apr 2021 01:25:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:07:32
User closed query 'Per source worksheet for Safety Call Day 149 Telephone Visit Date recorded as 05-JAN-2021 and EDC has 08-JAN-2021. Please clarify Visit date and update as applicable/' (Site from CRA).		20 Apr 2021 21:07:29
Query 'Per source worksheet for Safety Call Day 149 Telephone Visit Date recorded as 05-JAN-2021 and EDC has 08-JAN-2021. Please clarify Visit date and update as applicable/' answered with 'updated' (Site from CRA).		08 Apr 2021 16:36:34
DataPoint Un-verified.		08 Apr 2021 16:36:30
User entered '05 Jan 2021' reason for change: Data Entry Error		08 Apr 2021 16:36:30
DataPoint Verified.		07 Apr 2021 23:14:04
User opened query 'Per source worksheet for Safety Call Day 149 Telephone Visit Date recorded as 05-JAN-2021 and EDC has 08-JAN-2021. Please clarify Visit date and update as applicable/' (Site from CRA).		07 Apr 2021 23:13:19
Signature has been broken.		07 Apr 2021 20:23:21
User entered '08 Jan 2021' reason for change: Data Entry Error		07 Apr 2021 20:23:21
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User entered '05 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:10
User entered empty.		25 Mar 2021 17:08:47

US3462101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:14:04
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 18:13:10
User entered empty.		25 Mar 2021 17:08:47

US3462101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:14:04
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:08:47

US3462101

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:14:22
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:08:53

US3462101

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
User entered 'I'	System	25 Mar 2021 17:08:53

US3462101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:16:43
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	06 Apr 2021 18:16:32
User entered 'Yes (Y)'	System	25 Mar 2021 17:09:30
	(b) (4), (b) (6)	25 Mar 2021 17:09:30

US3462101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
User signature succeeded.	Gregg Lucksinger (b) (4)	21 Apr 2021 01:25:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:08:27
User closed query 'Per source worksheet for Safety Call Day 179, Visit Date recorded as 05-FEB-2021 and EDC has 08-FEB-2021. Please clarify?' (Site from CRA).		20 Apr 2021 21:08:05
Query 'Per source worksheet for Safety Call Day 179 Visit Date recorded as 05-FEB-2021 and EDC has 08-FEB-2021. Please clarify?' answered with 'updated' (Site from CRA).		08 Apr 2021 16:35:37
DataPoint Un-verified.		08 Apr 2021 16:35:32
User entered '05 Feb 2021' reason for change: Data Entry Error		08 Apr 2021 16:35:32
DataPoint Verified.		07 Apr 2021 23:16:43
User opened query 'Per source worksheet for Safety Call Day 179, Visit Date recorded as 05-FEB-2021 and EDC has 08-FEB-2021. Please clarify?' (Site from CRA).		07 Apr 2021 23:15:52
Signature has been broken.		07 Apr 2021 20:23:33
User entered '08 Feb 2021' reason for change: Data Entry Error		07 Apr 2021 20:23:33
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User entered '05 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:16:32
User entered empty.		25 Mar 2021 17:09:30

US3462101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:16:43
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 18:16:32
User entered empty.		25 Mar 2021 17:09:30

US3462101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:16:43
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 19:12:28
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:09:30

US3462101

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
DataPoint Verified.		07 Apr 2021 23:16:52
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:09:37

US3462101

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:52:26
User entered 'I'	System	25 Mar 2021 17:09:37

US3462101

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:18:59
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:09:47

US3462101

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:18:59
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		26 Mar 2021 14:26:34
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'unknow why it was done out of range, per source document date it correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:09:55
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	25 Mar 2021 17:09:47
User entered '24 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 17:09:47

US3462101

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[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 07:59:36
DataPoint Verified.		07 Apr 2021 23:18:59
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:09:47

US3462101

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered 'VISIT4'	System	25 Mar 2021 17:09:47

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:12
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:12
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:12
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered empty.	System	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:12
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:12
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:12
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:12
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered empty.	System	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:12
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered empty.	System	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:12
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered empty.	System	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:12
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:04:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered empty.	System	01 Apr 2021 16:33:00

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36

US3462101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:39:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36

US3462101

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:21
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:10:02

US3462101

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:39:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:21
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:10:02

US3462101

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:29
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:10:13

US3462101

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:29
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:10:13

US3462101

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:29
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered '14:45'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:10:13

US3462101

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered '24 Mar 2021 14:45'	System	25 Mar 2021 17:10:13

US3462101

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
DataPoint Verified.		07 Apr 2021 23:19:35
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:10:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:10:19

US3462101

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:36
User entered 'I'	System	25 Mar 2021 17:10:19

US3462101

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:04:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 18:45:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 18:45:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 18:45:29
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 18:45:23
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:45:23

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:04:38
User entered '8 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:45:23

US3462101

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:04:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:45:23

US3462101

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:39:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:45:23

US3462101

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:23:44

US3462101

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:39:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 17:23:44

US3462101

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:17

US3462101

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:17

US3462101

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:17

US3462101

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

Form: Visit Date

Generated On: 09 Jun 2021 17:39:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 00:07:17

US3462101

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:38

US3462101

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 19:34:22
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:39
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:34:42
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:41:25

US3462101

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:38

US3462101

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		21 Apr 2021 19:34:22
User closed query 'Please complete "Under what version of the Protocol, Participant was unblinded"?' (Site from CRA).		21 Apr 2021 19:34:05
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:39
Query 'Please complete "Under what version of the Protocol, Participant was unblinded"?' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:35:10
User entered 'Amendment 6 or later (Amendment 6 or later)'		08 Apr 2021 16:34:42
User opened query 'Please complete "Under what version of the Protocol, Participant was unblinded"?' (Site from CRA).		07 Apr 2021 23:20:43
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:41:25

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:38

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:38

US3462101

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 01:41:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 00:07:38

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 01:41:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 00:07:38

US3462101

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:38

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
User entered empty.	System	18 Jan 2021 00:07:38

US3462101

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

Form: Unblinding

Generated On: 09 Jun 2021 17:39:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
User entered empty.	System	18 Jan 2021 00:07:38

US3462101

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:55

US3462101

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:55

US3462101

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:20:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '16:04'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:07:55

US3462101

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:39:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
User entered '12 Jan 2021 16:04'	System	18 Jan 2021 00:07:55

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:21:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:08:11

US3462101

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:54

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:21:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:08:11

US3462101

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:54

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
DataPoint Verified.		07 Apr 2021 23:21:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '15:42'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 00:08:11

US3462101

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:39:54

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:30
User entered '12 Jan 2021 15:42'	System	18 Jan 2021 00:08:11

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:39:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:27:56
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:13:24
Query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'no ae occurred' (Site from DM).		08 Apr 2021 16:33:50
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		03 Apr 2021 16:33:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:34:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
Reviewed for Safety.		08 Oct 2020 12:10:28
User entered 'USA-US093-2020-mRNA-1273-P301000005'	System	08 Oct 2020 12:10:25
User entered 'New'	(b) (4), (b) (6)	08 Oct 2020 12:10:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 00:13:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 00:13:17
Data point term sent to Coder	System	08 Oct 2020 00:11:58
Coding entries removed.	Danuel Hamlin (b) (4)	08 Oct 2020 00:11:27
User entered 'Transient Ischemic Attack' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	08 Oct 2020 00:11:27
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: TIA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 22:14:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 22:14:58
Data point term sent to Coder	System	07 Oct 2020 18:52:24
User entered 'Patient was diagnosed of a TIA on the 25th September 2020. Symptoms was resolved within 24hours. He spent overnight in a health facility. Discharged the aspirin and atorvastatin.'	(b) (4), (b) (6)	07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered 'Yes (Y)'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered 'No (N)' reason for change: Data Entry Error		07 Oct 2020 19:00:12
User entered 'Yes (Y)'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered 'No (N)'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User closed query 'Data is required. Please complete.' (Site from System).		20 Oct 2020 18:34:18
User entered '25 Sep 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	08 Oct 2020 00:11:27
Query 'Data is required. Please complete.' answered with 'Data entry error. it was not a solicited adverse reaction' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 19:02:50
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:01:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Oct 2020 19:01:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:01:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Oct 2020 19:00:12
User entered ' Sep ' (non-conformant).	(b) (4), (b) (6)	07 Oct 2020 19:00:12
User entered '25 Sep 2020'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		20 Oct 2020 18:34:27
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'CONFIRMED.' (Site from System).	Danuel Hamlin (b) (4)	08 Oct 2020 00:11:55
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Oct 2020 00:11:27
User entered '06:00' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	08 Oct 2020 00:11:27
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Oct 2020 19:03:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:03:18
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Oct 2020 19:00:12
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'AE started 15 days after second IP.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 18:55:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Oct 2020 18:54:14
User entered ':00' (non-conformant).	(b) (4), (b) (6)	07 Oct 2020 18:54:14
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Oct 2020 18:52:03
User entered '07:00'	(b) (4), (b) (6)	07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 06:00'	System	08 Oct 2020 00:11:27
User entered empty.	System	07 Oct 2020 19:01:16
User entered ' Sep :00' (non-conformant).	System	07 Oct 2020 19:00:12
User entered '25 Sep 2020 :00' (non-conformant).	System	07 Oct 2020 18:54:14
User entered '25 Sep 2020 07:00'	System	07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered 'No (N)'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered '25 Sep 2020'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).		20 Oct 2020 18:34:29
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'CONFIRMED' (Site from System).	Danuel Hamlin (b) (4)	08 Oct 2020 00:12:01
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	08 Oct 2020 00:11:27
User entered '18:00' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	08 Oct 2020 00:11:27
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	07 Oct 2020 18:54:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:54:14
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	07 Oct 2020 18:52:03
User entered '12:00'	(b) (4), (b) (6)	07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 18:00'	System	08 Oct 2020 00:11:27
User entered empty.	System	07 Oct 2020 18:54:14
User entered '25 Sep 2020 12:00'	System	07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 00:18:06
Comment added 'Edit grade because he was hospitalized over night'.		07 Oct 2020 22:26:54
User entered 'Grade 4 (Grade 4)' reason for change:		07 Oct 2020 22:26:10
Data Entry Error		
Comment added 'severity should grade 2. He was hospitalized over night'.		07 Oct 2020 19:51:14
User entered 'Grade 1/Mild (Grade 1/Mild)'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	07 Oct 2020 18:57:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:57:29
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	07 Oct 2020 18:57:07
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:54:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:54:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:54:14
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:52:03
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered '0'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered '0'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Oct 2020 18:57:07
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	07 Oct 2020 18:57:07
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:57:07
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Oct 2020 18:52:03
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered '25 Sep 2020'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered '26 Sep 2020'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered 'No (N)'		07 Oct 2020 18:52:03

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered empty.		07 Oct 2020 18:52:03

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Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered '0'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered '0'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered '0'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered 'Not Related (NOT RELATED)'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered 'Not Related (NOT RELATED)'		07 Oct 2020 18:52:03

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Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:54:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:54:14
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:54:14
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:52:03
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:52:03

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Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered '0'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered 'I'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered '0'		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		07 Oct 2020 18:52:03

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:18:06
User entered empty.		07 Oct 2020 18:52:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
User closed query 'PV Query: Thank you for your response. Once discharge is redacted please send to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:42:05
Query 'PV Query: Thank you for your response. Once discharge is redacted please send to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'DISCHARGE SUMMARY SENT 11 MAR 2021 VIA EMAIL.' (Site from Safety).		11 Mar 2021 17:08:28
User closed query 'PV Query: Thank you for your response. MH page has not been updated. Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		05 Feb 2021 18:22:56
Query 'PV Query: Thank you for your response. MH page has not been updated. Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'Event happened during study not prior to study their for no need to add to MH' (Site from Safety).		04 Feb 2021 18:31:00
User opened query 'PV Query: Thank you for your response. Once discharge is redacted please send to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		13 Nov 2020 17:45:37
User opened query 'PV Query: Thank you for your response. MH page has not been updated. Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		13 Nov 2020 17:44:25

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative indicates that the subject underwent CT SCAN, MRI, AND ECHOCARDIOGRAM. However, there are no corresponding Concomitant Procedure record that match this information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:38:07
User closed query 'PV Query: Concomitant medication omeprazole had listed route of "topical". Please confirm the medication route.' (Site from Safety).		07 Nov 2020 00:03:00
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		06 Nov 2020 23:57:10
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		06 Nov 2020 23:57:07
Query 'PV Query: Concomitant medication omeprazole had listed route of "topical". Please confirm the medication route.' answered with 'Corrected.' (Site from Safety).		06 Nov 2020 20:05:39
User opened query 'PV Query: Concomitant medication omeprazole had listed route of "topical". Please confirm the medication route.' (Site from Safety).		06 Nov 2020 14:01:36
DataPoint Verified.		06 Nov 2020 00:18:06
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'WE RECEIVED DISCHARGE SUMMARY ON 11/04/2020. WE WILL EMAIL OR FAX COPY WHEN REDACTED' (Site from Safety).		05 Nov 2020 20:19:02

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'MH PRIOR TO ONSET OF STUDY WILL BE ADDED (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 20:02:07
User closed query 'PV Query: Was there an evaluation of hypercoagulability (e.g. protein C and S deficiency)?' (Site from Safety).		03 Nov 2020 14:22:04
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		03 Nov 2020 14:21:58
Query 'Per DM CLR: SAE Narrative indicates that the subject underwent CT SCAN, MRI, AND ECHOCARDIOGRAM. However, there are no corresponding Concomitant Procedure record that match this information. Please update to record the procedures as appropriate. Otherwise, clarify.' answered with 'PROCEDURES ADDED' (Site from DM).		02 Nov 2020 23:40:21
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'CON MEDS UPDATED' (Site from Safety).		02 Nov 2020 23:10:15
Query 'PV Query: Was there an evaluation of hypercoagulability (e.g. protein C and S deficiency)?' answered with 'HYPERCOAGUABLE WORKUP WAS NOT DONE AS PER LABS PROVIDED ' (Site from Safety).		02 Nov 2020 22:28:36
User closed query 'PV Query: Was there a consultation with a neurologist? If so, please provide consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).		02 Nov 2020 16:08:47

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Was there a consultation with a neurologist? If so, please provide consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'No neurologist was consulted' (Site from Safety).	(b) (4), (b) (6)	01 Nov 2020 15:38:04
User closed query 'PV Query: Was an MR angio performed? If so, please provide results. If unable to fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).		30 Oct 2020 13:17:31
User closed query 'PV Query: Was a carotid ultrasound performed? If so, please provide results. If unable to fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).		30 Oct 2020 13:17:28
User closed query 'PV Query: Did the subject have atrial fibrillation?' (Site from Safety).		30 Oct 2020 13:17:25
User closed query 'PV Query: Please provide results of echocardiogram and EKG. If unable to fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).		30 Oct 2020 13:17:22
User closed query 'PV query: Please provide result of Covid testing from hospitalization. If not performed, please state this.' (Site from Safety).		30 Oct 2020 13:17:19
User closed query 'PV Query: Please confirm if symptoms resolved on 25 Sep 2020. If not, please provide the date of resolution of symptoms.' (Site from Safety).		30 Oct 2020 13:17:16
User closed query 'PV Query: Please provide any known risk factors the subject had for atherosclerosis and TIA.' (Site from Safety).		30 Oct 2020 13:17:12
User closed query 'PV Query: Please provide lipid panel with date, results, unit and reference range.' (Site from Safety).		30 Oct 2020 13:17:09

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Was an MR angio performed? If so, please provide results. If unable to fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'MR ANGIO WAS NOT PERFORMED BUT CT ANGIO DONE DID NOT REVEALED LARGE VESSEL OCCLUSION WITHIN INTRACRANIAL ARTERIES NOR NECK ARTERIES STENOSIA OR DISSECTION' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 22:29:22
Query 'PV Query: Was a carotid ultrasound performed? If so, please provide results. If unable to fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'CTA HEAD AND NECK REVEALED 1. NO STENOSES OR DISSECTION OF THE ARTERIES OF YHE NECK. 2.NO LARGE VESSEL OCCLUSION WITHIN THE INTRACRANIAL ARTERIES.' (Site from Safety).		29 Oct 2020 22:23:55
Query 'PV Query: Please provide any known risk factors the subject had for atherosclerosis and TIA.' answered with 'HIGH CHOLESTEROL' (Site from Safety).		29 Oct 2020 22:03:59
Query 'PV Query: Please provide lipid panel with date, results, unit and reference range.' answered with 'TRIGLYCERIDE 299MG/DL(30-149MG/DL).CHOLESTEROL 222MG/DL(<200MG/DL) HDL 35MG/DL (>=40MG/DL). LDL 127MG/DL(<100MG/DL) DATE 9/25/2020' (Site from Safety).		29 Oct 2020 22:01:18
Query 'PV Query: Please provide results of echocardiogram and EKG. If unable to fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'EKG DONE WAS INTERPRETED AS ATRIAL FIBRILLATION BUT ECHO DONE LATER FOUND SINUS RHYTHM AT 60 BEATS PER MINUTE. CONCLUSION WAS NORMAL TRANSTHORACIC ECHO' (Site from Safety).		29 Oct 2020 21:48:54

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide result of Covid testing from hospitalization. If not performed, please state this.' answered with 'COVID TESTING DONE WAS NEGATIVE . SARS2-CoV-2 IgG Ab,S DONE WERE NEGATIVE' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 21:16:13
Query 'PV Query: Did the subject have atrial fibrillation?' answered with 'no patient did not have atrial fibrillation' (Site from Safety).		29 Oct 2020 21:13:32
Query 'PV Query: Please confirm if symptoms resolved on 25 Sep 2020. If not, please provide the date of resolution of symptoms.' answered with 'symptoms did resolved on that date. Currently subject is asymptomatic' (Site from Safety).		29 Oct 2020 21:12:36
User opened query 'Per DM CLR: SAE Narrative indicates that the subject underwent CT SCAN, MRI, AND ECHOCARDIOGRAM. However, there are no corresponding Concomitant Procedure record that match this information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).		29 Oct 2020 00:07:22
User opened query 'PV Query: Was an MR angio performed? If so, please provide results. If unable to fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).		19 Oct 2020 12:13:32
User opened query 'PV Query: Was there a consultation with a neurologist? If so, please provide consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).		19 Oct 2020 12:13:25
User opened query 'PV Query: Was there an evaluation of hypercoagulability (e.g. protein C and S deficiency)?' (Site from Safety).		19 Oct 2020 12:13:18
User opened query 'PV Query: Was a carotid ultrasound performed? If so, please provide results. If unable to fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).		19 Oct 2020 12:13:11
User opened query 'PV Query: Did the subject have atrial fibrillation?' (Site from Safety).		19 Oct 2020 12:13:04

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of echocardiogram and EKG. If unable to fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 12:12:53
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		16 Oct 2020 14:51:01
User opened query 'PV query: Please provide result of Covid testing from hospitalization. If not performed, please state this.' (Site from Safety).		16 Oct 2020 14:32:30
User opened query 'PV Query: Please confirm if symptoms resolved on 25 Sep 2020. If not, please provide the date of resolution of symptoms.' (Site from Safety).		16 Oct 2020 14:32:17
User opened query 'PV Query: Please provide any known risk factors the subject had for atherosclerosis and TIA.' (Site from Safety).		16 Oct 2020 14:31:45
User opened query 'PV Query: Please provide lipid panel with date, results, unit and reference range.' (Site from Safety).		16 Oct 2020 14:31:38
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		16 Oct 2020 14:31:31
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		16 Oct 2020 14:31:23

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT IS A 45 YEAR OLD MALE RANDOMIZED ON 10AUG2020 WITH 2ND DOSE ADMINISTERED AS PER ROUTINE ON 10SEP2020. PATIENT WOKE UP MORNING OF 25SEP2020 WITH POOR BALANCE, DIFFICULTY SPEAKING, AND WAS STRUGGLING TO WALK. PATIENT WENT TO EMERGENCY ROOM FOR EVALUATION. PATIENT RECEIVED WORK UP WITH CT SCAN, MRI, AND ECHOCARDIOGRAM ON 25SEP2020. ALL SCANS WERE CONSIDERED UNREMARKABLE. PATIENT WAS DIAGNOSED WITH PRESUMPTIVE TIA AND ADMITTED FOR OBSERVATION. PATIENT WAS DISCHARGED 26SEP2020 ON ANTIPLATELET AND STATIN THERAPY . PATIENT IS SCHEDULED FOR FOLLOW-UP EVALUATION WITH CARDIOLOGIST.' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	08 Oct 2020 00:11:27
User entered 'Patient was diagnosed of a TIA 15 days after IP. spent overnight in hospital and discharged with aspirin and atorvastatin. currently back to his baseline. will be seen by PI on 10/7/2020. Medical records will be obtained for further assessment.'	(b) (4), (b) (6)	07 Oct 2020 18:52:03

US3462101

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:57:29
User entered '0'	System	07 Oct 2020 18:54:14

US3462101

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Oct 2020 18:52:03

US3462101

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:39:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 18:52:03

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:55:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:55:44
Data point term sent to Coder	System	19 Apr 2021 17:54:01
User entered 'hyperlipidemia'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:53:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:53:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:53:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:53:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	19 Apr 2021 17:53:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:53:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:09:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:25
User entered 'Subject was diagnosed with hyperlipidemia after date of consent. Treated with atorvastatin. com meds updated'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 17:53:33

US3462101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:39:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 17:53:33

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:39:54

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:27:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User closed query 'SAE source medical history states many more con-meds such as Cholecalciferol is missing. Please update as needed. Thanks' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:57:25
Query 'SAE source medical history states many more con-meds such as Cholecalciferol is missing. Please update as needed. Thanks' answered with 'UPDATED' (Site from CRA).		08 Nov 2020 23:58:06
User opened query 'SAE source medical history states many more con-meds such as Cholecalciferol is missing. Please update as needed. Thanks' (Site from CRA).		06 Nov 2020 00:30:51
DataPoint Verified.		06 Nov 2020 00:23:23
User closed query 'Per CDM: DiaryDose 2, Temperature Day Log Line 3, diary reports medication was taken for pain or fever. Site response indicates 'Subject used 500mg Tylenol and Advil 600mg once on day2 for pain'; however these medications has not been recorded in concomitant medication page. Please add the con med else provid explanation in query response. Thank you' (Site from DM).		29 Oct 2020 14:04:05
Query 'Per CDM: DiaryDose 2, Temperature Day Log Line 3, diary reports medication was taken for pain or fever. Site response indicates 'Subject used 500mg Tylenol and Advil 600mg once on day2 for pain'; however these medications has not been recorded in concomitant medication page. Please add the con med else provide explanation in query response. Thank you' answered with 'WILL UPDATE' (Site from DM).		22 Oct 2020 16:20:11

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN EC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 19:07:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 19:07:46
Data point term sent to Coder	System	04 Feb 2021 18:34:42
Coding entries removed.	(b) (4), (b) (6)	04 Feb 2021 18:34:25
DataPoint Verified.	(b) (4)	06 Nov 2020 00:31:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN EC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 22:36:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 22:36:34
Data point term sent to Coder	System	07 Oct 2020 19:41:14
User entered 'Aspirin(EC)'	(b) (4), (b) (6)	07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:22:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:11:12
User entered 'Yes (Y)' reason for change: Data Entry Error		09 Feb 2021 18:11:12
DataPoint Verified.		06 Nov 2020 00:31:06
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 19:46:15
User entered 'Yes (Y)'		07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:22:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User closed query 'Per CDM re-query: Indication reflects Prophylaxis however the Prophylaxis field is recorded as 'NO'. Please review and update either indication or prophylaxis field as appropriate else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:31:40
Query 'Per CDM re-query: Indication reflects Prophylaxis however the Prophylaxis field is recorded as 'NO'. Please review and update either indication or prophylaxis field as appropriate else clarify. ' answered with 'Updated as Prophylaxis' (Site from DM).		09 Feb 2021 18:11:24
User closed query 'Per DM CLR: Please note that this CM is given after TIA has been resolved. Review indication and reconcile as appropriate. ' (Site from DM).		05 Feb 2021 12:10:44
User opened query 'Per CDM re-query: Indication reflects Prophylaxis however the Prophylaxis field is recorded as 'NO'. Please review and update either indication or prophylaxis field as appropriate else clarify. ' (Site from DM).		05 Feb 2021 12:10:42
Query 'Per DM CLR: Please note that this CM is given after TIA has been resolved. Review indication and reconcile as appropriate. ' answered with 'updated' (Site from DM).		04 Feb 2021 18:34:41
DataPoint Un-verified.		04 Feb 2021 18:34:25
User entered 'Prophylaxis for TIA' reason for change: Data Entry Error		04 Feb 2021 18:34:25
User opened query 'Per DM CLR: Please note that this CM is given after TIA has been resolved. Review indication and reconcile as appropriate. ' (Site from DM).		20 Nov 2020 08:54:23
DataPoint Verified.		06 Nov 2020 00:31:06

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User entered 'TIA'	(b) (4), (b) (6)	07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '81'		07 Oct 2020 19:41:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'mg (mg)'		07 Oct 2020 19:41:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		07 Oct 2020 19:41:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'once daily (QD)'		07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Oral (ORAL)'		07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '26 Sep 2020'		07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:22:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 12:08:53
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated to no as it did not match solicited event' (Site from DM).		04 Feb 2021 18:35:08
DataPoint Un-verified.		04 Feb 2021 18:34:25
User entered 'No (N)' reason for change: Data Entry Error		04 Feb 2021 18:34:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Event for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 08:54:35
		06 Nov 2020 00:31:06
User entered 'Yes (Y)'		07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 19:41:02

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 19:12:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 19:12:46
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	04 Feb 2021 18:36:45 04 Feb 2021 18:36:44
DataPoint Verified.		06 Nov 2020 00:31:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 22:48:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 22:48:24
Data point term sent to Coder	System	07 Oct 2020 19:44:26
Data point term sent to Coder	System	07 Oct 2020 19:43:24
User entered 'Atorvastatin'	(b) (4), (b) (6)	07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:11:34
User entered 'Yes (Y)' reason for change: Data Entry Error		09 Feb 2021 18:11:34
DataPoint Verified.		06 Nov 2020 00:31:06
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 19:46:27
User entered 'Yes (Y)'		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:23:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User closed query 'Per CDM re-query: Indication reflects Prophylaxis however the Prophylaxis field is recorded as 'NO'. Please review and update either indication or prophylaxis field as appropriate else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:31:47
Query 'Per CDM re-query: Indication reflects Prophylaxis however the Prophylaxis field is recorded as 'NO'. Please review and update either indication or prophylaxis field as appropriate else clarify. ' answered with 'updated as prophylaxis' (Site from DM).		09 Feb 2021 18:12:23
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication(HYPERLIPIDEMIA). 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).		05 Feb 2021 12:11:56
User opened query 'Per CDM re-query: Indication reflects Prophylaxis however the Prophylaxis field is recorded as 'NO'. Please review and update either indication or prophylaxis field as appropriate else clarify. ' (Site from DM).		05 Feb 2021 12:11:54
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication(HYPERLIPIDEMIA). Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Updated as Prophylaxis for the AE condition , medication was giving to subject after ER visit to try and prevent any Symptoms' (Site from DM).		04 Feb 2021 18:37:40
DataPoint Un-verified.		04 Feb 2021 18:36:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User entered 'Prophylaxis for TIA/HYPERLIPIDEMIA' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 18:36:44
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication(HYPERLIPIDEMIA). 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). DataPoint Verified.		20 Nov 2020 09:13:20
		06 Nov 2020 00:31:06
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:43:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:43:35
User entered 'TIA/Hyperlipidemia' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:43:35
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:42:45
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '80'		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'mg (mg)'		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'once daily (QD)'		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Oral (ORAL)'		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '26 Sep 2020'		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:23:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 12:12:09
DataPoint Un-verified.		04 Feb 2021 18:37:49
		04 Feb 2021 18:36:44
User entered 'No (N)' reason for change: Data Entry Error		04 Feb 2021 18:36:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 09:13:54
		06 Nov 2020 00:31:06
User entered 'Yes (Y)'		07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 19:42:45

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
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)	19 Oct 2020 21:25:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:25:32
Data point term sent to Coder	System	19 Oct 2020 21:24:35
User entered 'Influenza Vaccine'	(b) (4), (b) (6)	19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (p) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Annual Prophylaxis'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0.5'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'mL (mL)'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'once (ONCE)'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Intramuscular (INTRAMUSCULAR)'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '06 Oct 2020'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '06 Oct 2020'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User entered empty.	System	19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User entered empty.	System	19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:19
User entered empty.	System	19 Oct 2020 21:23:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:23:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:23:15
Data point term sent to Coder	System	22 Oct 2020 16:22:32
User entered 'ADVIL'	(b) (4), (b) (6)	22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
DataPoint Verified.		07 Apr 2021 23:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:43
User closed query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to as there is an solicited adverse reaction recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:35:22
Query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to as there is an solicited adverse reaction recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. ' answered with 'ENTRY ERROR' (Site from DM).		11 Mar 2021 16:40:47
Signature has been broken.		11 Mar 2021 16:40:27
User entered 'No (N)' reason for change: Data Entry Error		11 Mar 2021 16:40:27
User opened query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to as there is an solicited adverse reaction recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. ' (Site from DM).		28 Feb 2021 15:14:24
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:12:39
User entered 'Yes (Y)' reason for change: Data Entry Error		09 Feb 2021 18:12:39
DataPoint Verified.		06 Nov 2020 00:31:06

PRODUCTION RELEASE (v12.003
EAB) (1725)

1790 of 2047

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User closed query 'Per DM CLR-RQ: Response noted. However, please note that there is a record of Injection site pain in the diary during the CM's timeframe. Please review condition and review if this met any AE reporting criteria per protocol 8.3.4. If n AE recording criteria is met, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).		19 Apr 2021 10:44:02
Query 'Per DM CLR-RQ: Response noted. However, please note that there is a record of Injection site pain in the diary during the CM's timeframe. Please review condition and review if this met any AE reporting criteria per protocol 8.3.4. If no AE recording criteria is met, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'REVIEWED , NOT CONSIDERED AE' (Site from DM).		07 Apr 2021 17:53:17
User opened query 'Per DM CLR-RQ: Response noted. However, please note that there is a record of Injection site pain in the diary during the CM's timeframe. Please review condition and review if this met any AE reporting criteria per protocol 8.3.4. If n AE recording criteria is met, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).		01 Apr 2021 05:09:37
Query 'Per DM CLR-RQ: Response noted. However, please note that there is a record of Injection site pain in the diary during the CM's timeframe. Please review condition and review if this met any AE reporting criteria per protocol 8.3.4. If no AE recording criteria is met, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. Else, please record condition in AE ecrf. ' canceled (Site from DM).		01 Apr 2021 05:09:29

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, please note that there is a record of Injection site pain in the diary during the CM's timeframe. Please review condition and review if this met any AE reporting criteria per protocol 8.3.4. If n AE recording criteria is met, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. Else, please record condition in AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:09:10
User closed query 'Per DM CLR-Requery: Response noted. However, please review if PAIN AROUND VACCINE SITE met any of the AE reporting criteria stated in protocol 8.3.4. If so, update AE ecrf to include this condition. Else, confirm in query response that indication did not meet AE reporting criteria.' (Site from DM).		12 Mar 2021 14:35:51
Query 'Per DM CLR-Requery: Response noted. However, please review if PAIN AROUND VACCINE SITE met any of the AE reporting criteria stated in protocol 8.3.4. If so, update AE ecrf to include this condition. Else, confirm in query response that indication did not meet AE reporting criteria.' answered with 'not consider AE' (Site from DM).		11 Mar 2021 16:40:22
User opened query 'Per DM CLR-Requery: Response noted. However, please review if PAIN AROUND VACCINE SITE met any of the AE reporting criteria stated in protocol 8.3.4. If so, update AE ecrf to include this condition. Else, confirm in query response that indication did not meet AE reporting criteria.' (Site from DM).		08 Mar 2021 08:55:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User closed query 'Per CDM re-query: Response noted; Please confirm in query response that the 'PAIN AROUND VACCINE SITE' doesn't meet any of the AE reporting criteria mentioned in previous query. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM re-query: Response noted; Please confirm in query response that the 'PAIN AROUND VACCINE SITE' doesn't meet any of the AE reporting criteria mentioned in previous query. Thank you ' answered with 'updated as prophylaxis' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 18:12:54
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AROUND VACCINE SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AROUND VACCINE SITE did not meet the AE reporting criteria.' (Site from DM).		05 Feb 2021 12:14:07
User opened query 'Per CDM re-query: Response noted; Please confirm in query response that the 'PAIN AROUND VACCINE SITE' doesn't meet any of the AE reporting criteria mentioned in previous query. Thank you ' (Site from DM).		05 Feb 2021 12:14:05
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AROUND VACCINE SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AROUND VACCINE SITE did not meet the AE reporting criteria.' answered with 'not an AE subject just let us know they took med for pain o the injection area' (Site from DM).		04 Feb 2021 18:41:12

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AROUND VACCINE SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AROUND VACCINE SITE did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 17:02:37
		06 Nov 2020 00:31:06
User entered 'PAIN AROUND VACCINE SITE'		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '600'		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'mg (mg)'		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'once (ONCE)'		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Oral (ORAL)'		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '11 Sep 2020'		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '11 Sep 2020'		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
DataPoint Verified.		07 Apr 2021 23:23:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in the eDiary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 12:12:23
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in the eDiary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'updated' (Site from DM).		04 Feb 2021 18:41:29
DataPoint Un-verified.		04 Feb 2021 18:41:21
User entered 'Yes (Y)' reason for change: Data Entry Error		04 Feb 2021 18:41:21
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in the eDiary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).		06 Jan 2021 17:02:54
DataPoint Verified.		06 Nov 2020 00:31:06
User entered 'No (N)'		22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User entered empty.	System	22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User entered empty.	System	22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:22
User entered empty.	System	22 Oct 2020 16:22:25

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE, PRODUCTSYNONYM: LAMICTAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:06:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:06:29
Data point term sent to Coder User entered 'LAMICTAL'	System (b) (4), (b) (6)	02 Nov 2020 22:34:17 02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'BIPOLAR'		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '200'		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'mg (mg)'		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'four times daily (QID)'		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 22:33:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 22:33:54
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 22:33:54
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 22:33:42
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'UN UNK 2002'		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 22:33:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:32:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:32:08
Data point term sent to Coder	System	02 Nov 2020 22:41:23
User entered 'LEXAPRO'	(b) (4), (b) (6)	02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'ANXIETY'		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '20'		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'mg (mg)'		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'once daily (QD)'		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Oral (ORAL)'		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'UN UNK 1992'		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 22:40:42

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:07:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:07:25
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	06 Nov 2020 20:06:14 06 Nov 2020 20:05:25
DataPoint Verified.		06 Nov 2020 00:31:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 06:00:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 06:00:14
Data point term sent to Coder	System	02 Nov 2020 22:44:27
User entered 'OMEPRAZOLE'	(b) (4), (b) (6)	02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'GERD'		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '20'		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'mg (mg)'		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'once daily (QD)'		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:23:59
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:05:25
User entered 'Oral (ORAL)' reason for change: Data Entry Error		06 Nov 2020 20:05:25
DataPoint Verified.		06 Nov 2020 00:31:06
User entered 'Topical (TOPICAL)'		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'UN UNK 2019'		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 22:43:57

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: NORTRIPTYLINE HYDROCHLORIDE, PRODUCTSYNONYM: PAMELOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:04:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:04:58
Data point term sent to Coder	System	02 Nov 2020 22:50:32
User entered 'PAMELOR'	(b) (4), (b) (6)	02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'ANXIETY'		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '10'		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'mg (mg)'		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'four times daily (QID)'		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Oral (ORAL)'		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'UN UNK 1998'		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 22:49:32

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:11:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:11:24
Data point term sent to Coder	System	02 Nov 2020 22:52:35
User entered 'MULTIVITAMINS'	(b) (4), (b) (6)	02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'SUPPLEMENTATION'		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'I'		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'tablet (TABLET)'		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'once daily (QD)'		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Oral (ORAL)'		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'UN UNK 2010'		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 22:51:55

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 06:13:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 06:13:13
Data point term sent to Coder	System	02 Nov 2020 22:54:37
User entered 'VITAMIN B-12'	(b) (4), (b) (6)	02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 22:54:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 22:54:23
User entered 'SUPPLEMENTATION' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 22:54:23
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 22:54:07
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '1000'		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'ug (ug)'		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'once daily (QD)'		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Oral (ORAL)'		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'UN UNK 2019'		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 22:54:07

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: OYST-CAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 06:01:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 06:01:13
Data point term sent to Coder	System	02 Nov 2020 23:08:50
User entered 'oyst-cal-500'	(b) (4), (b) (6)	02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'supplementation'		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '1250'		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'mg (mg)'		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'twice daily (BID)'		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Oral (ORAL)'		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'UN UNK 2012'		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered '0'		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'Yes (Y)'		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered empty.		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:06
User entered 'No (N)'		02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 23:08:08

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 00:00:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 00:00:36
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	08 Nov 2020 23:59:21 08 Nov 2020 23:58:57
User entered 'VITAMIN D3' reason for change: Data Entry Error		08 Nov 2020 23:58:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 23:57:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 23:57:36
Data point term sent to Coder	System	08 Nov 2020 23:57:20
User entered 'VITAMIN D'	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Nov 2020 23:56:44
User entered 'SUPPLEMENTS' reason for change:	(b) (4), (b) (6)	08 Nov 2020 23:56:44
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Nov 2020 23:56:26
User entered empty.	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '1000' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Nov 2020 23:58:57
User entered '1'		08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Nov 2020 23:58:57
User entered 'tablet (TABLET)'		08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered empty.	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered empty.	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered empty.	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:54
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'UN UNK 2012'	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '0'	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:24:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:25:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered empty.	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:25:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'No (N)'	(b) (4), (b) (6)	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Nov 2020 23:56:26

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
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)	09 Nov 2020 00:03:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Nov 2020 00:03:37
Data point term sent to Coder	System	09 Nov 2020 00:03:21
User entered 'INFLUENZA VACCINE'	(b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'IMMUNIZATION'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '0.5'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
DataPoint Verified.		07 Apr 2021 23:25:19
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
User entered empty.	System	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
User entered empty.	System	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:39:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:19:12
User entered empty.	System	09 Nov 2020 00:02:44

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:39:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:27:56
DataPoint Verified.		07 Apr 2021 23:25:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 23:23:01

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:39:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered '26 Sep 2020'		02 Nov 2020 23:24:57

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:39:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered 'MRI BRAIN WO'		02 Nov 2020 23:24:57

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered 'Adverse Event (AE)'		02 Nov 2020 23:24:57

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:39:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered empty.		02 Nov 2020 23:24:57

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:39:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:24
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered '26 Sep 2020'		02 Nov 2020 23:26:21

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:39:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:24
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered 'ECHO 2D COMPLETE DOPPLER'		02 Nov 2020 23:35:42
reason for change: Data Entry Error		
User entered 'ECHO 2D'		02 Nov 2020 23:26:21

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:24
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered 'Diagnostic (DIAGNOSTIC)'		02 Nov 2020 23:26:21

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:39:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:24
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered empty.		02 Nov 2020 23:26:21

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:39:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:26
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered '25 Sep 2020'		02 Nov 2020 23:28:28

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:39:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:26
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered 'CTA HEAD NECK'		02 Nov 2020 23:28:28

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:26
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered 'Diagnostic (DIAGNOSTIC)'		02 Nov 2020 23:28:28

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:39:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:26
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered empty.		02 Nov 2020 23:28:28

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:39:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:29
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered '25 Sep 2020'		02 Nov 2020 23:31:01

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:39:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:29
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered 'CT HEAD WO'		02 Nov 2020 23:31:01

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:29
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered 'Diagnostic (DIAGNOSTIC)'		02 Nov 2020 23:31:01

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:39:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:29
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered empty.		02 Nov 2020 23:31:01

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:39:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered '26 Sep 2020'		02 Nov 2020 23:37:16

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:39:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered 'ECG'		02 Nov 2020 23:37:16

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:39:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered 'Diagnostic (DIAGNOSTIC)'		02 Nov 2020 23:37:16

US3462101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:39:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:31:57
User entered empty.		02 Nov 2020 23:37:16

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'USA-US093-2020-MRNA-1273-P301000005'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Yes (Y)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Yes (Y)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Edward'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Kerwin'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		03 Nov 2020 14:25:00
User entered 'US'	System	08 Oct 2020 12:10:49

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
	(b) (4)	
User entered '3'	System	06 Nov 2020 23:57:42
User entered '2'	System	03 Nov 2020 14:25:13
User entered '1'	System	08 Oct 2020 12:10:49

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'USA-US093-2020-MRNA-1273-P301000005'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Yes (Y)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Yes (Y)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Edward'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Kerwin'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		03 Nov 2020 14:25:00
User entered 'US'	System	08 Oct 2020 12:10:49

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
	(b) (4)	
User entered '3'	System	06 Nov 2020 23:57:42
User entered '2'	System	03 Nov 2020 14:25:13
User entered '1'	System	08 Oct 2020 12:10:49

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:39:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
User entered '08/Oct/2020 08:10'	System	08 Oct 2020 12:10:49

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:39:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		03 Nov 2020 14:25:00
User entered 'I'		08 Oct 2020 12:10:49

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'USA-US093-2020-MRNA-1273-P301000005'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Yes (Y)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Yes (Y)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Edward'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Kerwin'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		03 Nov 2020 14:25:00
User entered 'US'	System	08 Oct 2020 12:10:49

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
	(b) (4)	
User entered '3'	System	06 Nov 2020 23:57:42
User entered '2'	System	03 Nov 2020 14:25:13
User entered '1'	System	08 Oct 2020 12:10:49

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:39:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
User entered '03/Nov/2020 09:25'	System	03 Nov 2020 14:25:13

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:39:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:57:30
DataPoint Verified.		06 Nov 2020 00:15:30
User entered 'I'		03 Nov 2020 14:25:13

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'USA-US093-2020-MRNA-1273-P301000005'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Yes (Y)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Yes (Y)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'No (N)'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Edward'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		08 Oct 2020 12:10:42
User entered 'Kerwin'	System	08 Oct 2020 12:10:25

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:15:30
Reviewed for Safety.		03 Nov 2020 14:25:00
User entered 'US'	System	08 Oct 2020 12:10:49

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:39:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
	(b) (4)	
User entered '3'	System	06 Nov 2020 23:57:42
User entered '2'	System	03 Nov 2020 14:25:13
User entered '1'	System	08 Oct 2020 12:10:49

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:39:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:57
User entered '06/Nov/2020 23:57'	System	06 Nov 2020 23:57:42

US3462101

Folder: SAE USA-US093-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:39:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:43:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:57
User entered 'I'		06 Nov 2020 23:57:42