

US3462364 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:40:11

All time stamps listed in this document are displayed in GMT

US3462364

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:38:10

Generated On: 09 Jun 2021 17:40:11

[Participant ID](#)

US3462364

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

US3462364

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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 01:59:15

Generated On: 09 Jun 2021 17:40:11

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input checked="" type="radio"/> Male <input 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 01:59:15

Generated On: 09 Jun 2021 17:40:11

Date of Informed Consent (<i>dd MMM yyyy</i>)	27 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 01:59:15

Generated On: 09 Jun 2021 17:40:11

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 01:59:15

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Condition	OCCASIONAL KIDNEY STONES LEFT KIDNEY
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Condition	URINARY TRACT INFECTIONS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Condition	OVARIAN CYST BOTH OVARIES
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Condition	TOTAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Condition	ALLERGY TO MORPHINE
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Condition	ALLERGY TO SULFA
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 19:25:43

Generated On: 09 Jun 2021 17:40:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:38 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:38
Height (<i>xxx.x</i>)	167.6 cm
Weight (<i>xxx.x</i>)	90.7 kg
BMI (<i>xxx.x</i>)	32.28935 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 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 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: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 01:59:15

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Date of assessment (dd MMM yyyy) 27 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☒
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2004

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

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

CONTACT TRACING WORKS
FOR (b) (6)

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 01:59:15

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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 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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 01:59:15

Generated On: 09 Jun 2021 17:40:11

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 188729

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 01:59:15

Generated On: 09 Jun 2021 17:40:11

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 01:59:15

Generated On: 09 Jun 2021 17:40:11

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)	27 AUG 2020
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:38
Temperature (xxx.x)	98.5 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)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 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 01:59:15

Generated On: 09 Jun 2021 17:40:11

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)	27 AUG 2020
Time of assessment (00:00-23:59)	13:03 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 13:03
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 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 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 12:33 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 12:33

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 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 AUG 2020
Collection time (00:00-23:59)	12:27 (24 HR)
Collection date and time (derived)	27 AUG 2020 12:27

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:27	27 AUG 2020 12:27
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 13:04

PC Open Date & Time

27 AUG 2020 12:53

PC Close Date & Time

27 AUG 2020 15:23

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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

97.9 °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

27 AUG 2020 19:07

PC Open Date & Time

27 AUG 2020 16:18

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

28 AUG 2020 19:10

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input 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	29 AUG 2020 19:02
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

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

97.4 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 AUG 2020 19:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

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

97.5 °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

31 AUG 2020 19:19

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

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

97.6 °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

01 SEP 2020 22:28

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

02 SEP 2020 18:59

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 8

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

03 SEP 2020 19:01

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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

27 AUG 2020 13:04

PC Open Date & Time

27 AUG 2020 12:53

PC Close Date & Time

27 AUG 2020 15:23

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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

27 AUG 2020 19:07

PC Open Date & Time

27 AUG 2020 16:18

PC Close Date & Time

28 AUG 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

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

28 AUG 2020 19:09

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

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

29 AUG 2020 19:03

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

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

30 AUG 2020 19:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

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

31 AUG 2020 19:20

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

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

01 SEP 2020 22:28

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

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

02 SEP 2020 18:59

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 13:05
PC Open Date & Time	27 AUG 2020 12:53
PC Close Date & Time	27 AUG 2020 15:23

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 19:08
PC Open Date & Time	27 AUG 2020 16:18
PC Close Date & Time	28 AUG 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 1935

EAB) (1725)

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 19:10
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

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

52 of 1935

EAB) (1725)

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:04
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

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

54 of 1935

EAB) (1725)

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 19:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

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

56 of 1935

EAB) (1725)

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 19:20
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 1935

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 22:29
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

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

60 of 1935

EAB) (1725)

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:00
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

- 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 ☐

PC Time Stamp	03 SEP 2020 19:01
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

03 SEP 2020 19:01

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3462364

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:11

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	03 SEP 2020 19:01
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3462364

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3462364

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:58:38

Generated On: 09 Jun 2021 17:40:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462364

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:58:38

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:58:38

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

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)	24 SEP 2020
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:01
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

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)	24 SEP 2020
Time of assessment (00:00-23:59)	10:57 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:57
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3462364

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 10:27 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 10:27

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

US3462364

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 SEP 2020
Collection time (00:00-23:59)	10:20 (24 HR)
Collection date and time (derived)	24 SEP 2020 10:20

US3462364

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:20	24 SEP 2020 10:20
Nasopharyngeal Swab 2	No		

US3462364

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 10:57

PC Open Date & Time

24 SEP 2020 10:47

PC Close Date & Time

24 SEP 2020 13:17

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 19:36

PC Open Date & Time

24 SEP 2020 14:12

PC Close Date & Time

25 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

25 SEP 2020 19:27

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

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

97.4 °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

27 SEP 2020 09:02

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 18:59

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 18:50

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

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

97.9 °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

29 SEP 2020 18:03

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

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

98.1 °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

30 SEP 2020 18:47

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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

24 SEP 2020 10:57

PC Open Date & Time

24 SEP 2020 10:47

PC Close Date & Time

24 SEP 2020 13:17

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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

24 SEP 2020 19:36

PC Open Date & Time

24 SEP 2020 14:12

PC Close Date & Time

25 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

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

25 SEP 2020 19:27

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

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

27 SEP 2020 09:03

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

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

27 SEP 2020 18:59

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

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

28 SEP 2020 18:50

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

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

29 SEP 2020 18:04

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

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

30 SEP 2020 18:48

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 10:58
PC Open Date & Time	24 SEP 2020 10:47
PC Close Date & Time	24 SEP 2020 13:17

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 19:37
PC Open Date & Time	24 SEP 2020 14:12
PC Close Date & Time	25 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 19:28
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 09:03
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

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 ☒

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:00
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

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 ☒

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EAB) (1725)

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 18:50
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 18:04
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 18:48
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3462364

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462364

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3462364

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462364

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

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) _____

US3462364

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

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.

US3462364

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 OCT 2020
Collection time (00:00-23:59)	13:15 (24 HR)
Collection date and time (derived)	22 OCT 2020 13:15

US3462364

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:59:15

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 12:01:15

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

05 NOV 2020 13:02:49

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

12 NOV 2020 08:53:53

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 96

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 17:59:40

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

07 DEC 2020 12:00:35

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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	12 DEC 2020 06:53:45
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

19 DEC 2020 08:34:40

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 08:23:53

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

05 JAN 2021 19:42:53

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

12 JAN 2021 18:07:18

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

16 JAN 2021 03:57:21

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 05:37:41

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

02 FEB 2021 17:59:32

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

08 FEB 2021 12:00:59

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

13 FEB 2021 08:05:14

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

22 FEB 2021 12:00:39

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

27 FEB 2021 07:24:29

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 12:04:58

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

15 MAR 2021 19:22:33

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

24 MAR 2021 11:59:27

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

27 MAR 2021 05:59:13

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

03 APR 2021 06:14:58

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

12 APR 2021 12:00:58

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

19 APR 2021 12:00:46

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

26 APR 2021 12:19:43

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

01 MAY 2021 07:23:24

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 271

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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="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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 390

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 <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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 495

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 FEB 2022 00:01
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Patient Cloud Close Date & Time	16 FEB 2022 23:59
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US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 705

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

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

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

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

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

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

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

Patient Cloud Open Date & Time	20 AUG 2022 00:01
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Patient Cloud Close Date & Time	24 AUG 2022 23:59
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US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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="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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 ☐

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3462364

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:40:11

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
Yes	No	27 FEB 2021 07:25:15

US3462364

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462364

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3462364

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3462364

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:09:31

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:23:12

Generated On: 09 Jun 2021 17:40:11

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) _____

US3462364

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

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.

US3462364

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

14:05 (24 HR)

Collection date and time (derived)

23 MAR 2021 14:05

US3462364

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462364

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:11

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"/>

US3462364

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:40:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3462364

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

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

Visit date (dd MMM yyyy)	18 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3462364

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 13:09:31

Generated On: 09 Jun 2021 17:40:11

Date of updated informed consent (<i>dd MMM yyyy</i>)	18 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	18 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3462364

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Height	167.6 cm
Weight	90.7 kg
BMI (xxx.x)	32.28935

US3462364

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Height	167.6 cm
Weight	90.7 kg
BMI (xxx.x)	32.28935
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)	18 JAN 2021
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 15:01
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3462364

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Height	167.6 cm
Weight	90.7 kg
BMI (xxx.x)	32.28935
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)	18 JAN 2021
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 16:15
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3462364

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3462364

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 18 JAN 2021

What was the treatment time? (00:00-23:59) 15:45 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 15:45

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

What was the frequency of the study treatment dosing? ONCE

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

US3462364

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

14:40 (24 HR)

Collection date and time (derived)

18 JAN 2021 14:40

US3462364

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 20:38:11

Generated On: 09 Jun 2021 17:40:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	14:24
Collection Date and Time (derived)	18 JAN 2021 14:24

US3462364

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:38:56

Generated On: 09 Jun 2021 17:40:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462364

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

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)	24 FEB 2021
Time of assessment (00:00-23:59)	13:08 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 13:08
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

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)	24 FEB 2021
Time of assessment (00:00-23:59)	13:54 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 13:54
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3462364

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 22:22:30

Generated On: 09 Jun 2021 17:40:11

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.

US3462364

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 22:22:30

Generated On: 09 Jun 2021 17:40:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 24 FEB 2021

What was the treatment time? (00:00-23:59) 13:24 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 13:24

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

US3462364

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:22:30

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3462364

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462364

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

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) _____

US3462364

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

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.

US3462364

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 22:22:31

Generated On: 09 Jun 2021 17:40:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	14:05 (24 HR)
Collection date and time (derived)	23 MAR 2021 14:05

US3462364

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 19:25:43

Generated On: 09 Jun 2021 17:40:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 18:18:49

Generated On: 09 Jun 2021 17:40:11

AEID	USA-US093-2021-MRNA-1273-P30 1000007
Adverse event	KIDNEY STONES
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)	6 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	8 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	7 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	9 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 18:18:49

Generated On: 09 Jun 2021 17:40:11

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

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 18:18:49

Generated On: 09 Jun 2021 17:40:11

ON 06FEB2021 PT REPORTED HAVING EXTREME BACK PAIN THAT PERSISTED ALL DAY. AROUND 1900 ON 06FEB2021 PT WENT INTO URGENT CARE IN GRANTS PASS, OREGON TO HAVE HER EXTREME BACK PAIN LOOKED AT. AT URGENT CARE PT WAS DIAGNOSED WITH HAVING KIDNEY STONES WHICH IS NOT UNUSUAL AS THE PT HAS A MEDICAL HISTORY OF HAVING KIDNEY STONES. THE FOLLOWING DAY 07FEB2021 THE PT WAS STILL IN EXTREME BACK PAIN AND RETURNED TO URGENT CARE AT 1900. PT WAS THEN TRANSPORTED VIA AMBULANCE TO PROVIDENCE MEDFORD MEDICAL CENTER AT AROUND 2100. PT STAYED IN HOSPITAL FROM 07FEB2021 TO 09FEB2021. ON 08FEB2021 PT HAD A LITHOTRIPSY PROCEDURE DONE TO REMOVE THE KIDNEY STONES. PT WAS PRESCRIBED 5MG OXYCODONE WHICH THE PT TOOK ONCE DAILY FROM 09FEB2021 TO 10FEB2021. PT REPORTS NO CURRENT SYMPTOMS AND EXTREME BACK PAIN HAS RESOLVED.

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

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 20:38:11

Generated On: 09 Jun 2021 17:40:11

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

Yes ☒

No ☐

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

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 20:07:02

Generated On: 09 Jun 2021 17:40:11

Name of Medication IBUPROFEN (3TABS)

Prophylaxis Yes ☐
No ☒

Indication INJECTION SIDE PAIN IN RIGHT
DELTOID

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 20:07:02

Generated On: 09 Jun 2021 17:40:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 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"/>

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 20:07:02

Generated On: 09 Jun 2021 17:40:11

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 20:07:02

Generated On: 09 Jun 2021 17:40:11

	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)		4 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)		4 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"/>

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 20:07:02

Generated On: 09 Jun 2021 17:40:11

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONES

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 20:07:02

Generated On: 09 Jun 2021 17:40:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 10 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 20:07:02

Generated On: 09 Jun 2021 17:40:11

Name of Medication MIGRAINE INJECTION
TREATMENT (SUMATRIPTAN
INJECTION)

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 20:07:02

Generated On: 09 Jun 2021 17:40:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2004
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input checked="" type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3462364

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 30 Apr 2021 20:07:02

Generated On: 09 Jun 2021 17:40:11

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3462364

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 May 2021 18:18:49

Generated On: 09 Jun 2021 17:40:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 FEB 2021	LITHOTRIPSY PROCEDURE	Adverse Event	

US3462364

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:40:11

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 17:40:11

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 ☐

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 19 Mar 2021 19:25:43

Generated On: 09 Jun 2021 17:40:11

SAEID	USA-US093-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	1

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Mar 2021 19:25:43

Generated On: 09 Jun 2021 17:40:11

SAEID	USA-US093-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	1
Date of submission (Pre-filled from custom function)	25/FEB/2021 14:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3462364 (Prod: Crisor, LLC)

US3462364

Form: Participant Creation

Generated On: 09 Jun 2021 17:40:11

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'US3462364'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 18:29:17

US3462364

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:51:23

US3462364

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 18:29:18

US3462364

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:51:23

US3462364

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'SCRN'	System	27 Aug 2020 19:51:23

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 18:29:19

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '66'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'YEARS'	System	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '66'	System	27 Aug 2020 19:51:49

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:27

US3462364

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:51:49

US3462364

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:11

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Aug 2020'	System	27 Aug 2020 19:51:49

US3462364

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:11

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '2020'	System	27 Aug 2020 19:51:49

US3462364

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:51:49

US3462364

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:11

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:51:49

US3462364

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:11

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:51:49

US3462364

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:51:49

US3462364

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:51:49

US3462364

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 18:29:18

US3462364

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'I'	System	27 Aug 2020 19:51:55

US3462364

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:40:11

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:51:55

US3462364

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:40:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:48:44

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 18:18:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 18:18:03
User closed query 'Per DM CLR: Please specify the location of OCCASIONAL KIDNEY STONES (e.g. right, left or both kidneys). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:20:03
Data point term sent to Coder	System	04 Nov 2020 16:31:46
Query 'Per DM CLR: Please specify the location of OCCASIONAL KIDNEY STONES (e.g. right, left or both kidneys). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:31:18
Coding entries removed.		04 Nov 2020 16:31:03
User entered 'OCCASIONAL KIDNEY STONES LEFT KIDNEY' reason for change: Data Entry Error		04 Nov 2020 16:31:03
User opened query 'Per DM CLR: Please specify the location of OCCASIONAL KIDNEY STONES (e.g. right, left or both kidneys). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		23 Sep 2020 19:10:20
User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 08:05:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 08:05:50

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	01 Sep 2020 00:49:37
User entered 'OCCASIONAL KIDNEY STONES'	(b) (4), (b) (6)	01 Sep 2020 00:49:08

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 1975'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:49:08

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:49:08

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:49:08

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:49:08

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:49:08

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Jan 1975'	System	01 Sep 2020 00:49:08

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '1975'	System	01 Sep 2020 00:49:08

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Sep 2020 00:49:08

US3462364

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Sep 2020 00:49:08

US3462364

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:51:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:51:36
Data point term sent to Coder	System	01 Sep 2020 00:50:37
User entered 'URINARY TRACT INFECTIONS'	(b) (4), (b) (6)	01 Sep 2020 00:49:52

US3462364

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:49:52

US3462364

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:49:52

US3462364

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:49:52

US3462364

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:49:52

US3462364

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:49:52

US3462364

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Jan 2010'	System	01 Sep 2020 00:49:52

US3462364

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '2010'	System	01 Sep 2020 00:49:52

US3462364

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Jan 2011'	System	01 Sep 2020 00:49:52

US3462364

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '2011'	System	01 Sep 2020 00:49:52

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 15:24:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 15:24:56
User closed query 'Per DM CLR: Please specify the location of the OVARIAN CYST (e.g. right, left or in both ovaries). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:03:07
User closed query 'Per DM CLR: Please update the condition to confirm if the OVARIAN CYST was benign or malignant, as well as location (e.g. right, left or in both ovaries). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		06 Nov 2020 09:03:05
Query 'Per DM CLR: Please specify the location of the OVARIAN CYST (e.g. right, left or in both ovaries). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Updated' (Site from DM).		04 Nov 2020 16:36:07
Query 'Per DM CLR: Please update the condition to confirm if the OVARIAN CYST was benign or malignant, as well as location (e.g. right, left or in both ovaries). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Updated' (Site from DM).		04 Nov 2020 16:36:02
Data point term sent to Coder	System	04 Nov 2020 16:35:55
Coding entries removed.	(b) (4), (b) (6)	04 Nov 2020 16:35:53

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

[Condition](#)

Audit	User	Time (GMT)
User entered 'OVARIAN CYST BOTH OVARIES'	(b) (4), (b) (6)	04 Nov 2020 16:35:53
reason for change: Data Entry Error		
User opened query 'Per DM CLR: Please specify the location of the OVARIAN CYST (e.g. right, left or in both ovaries). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		23 Sep 2020 19:11:07
User opened query 'Per DM CLR: Please update the condition to confirm if the OVARIAN CYST was benign or malignant, as well as location (e.g. right, left or in both ovaries). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		23 Sep 2020 19:10:54
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:52:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:52:37
Data point term sent to Coder	System	01 Sep 2020 00:51:38
User entered 'OVARIAN CYST'	(b) (4), (b) (6)	01 Sep 2020 00:51:05

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 1975'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:05

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:05

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:05

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:05

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:05

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Jan 1975'	System	01 Sep 2020 00:51:05

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '1975'	System	01 Sep 2020 00:51:05

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Jan 2004'	System	01 Sep 2020 00:51:05

US3462364

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '2004'	System	01 Sep 2020 00:51:05

US3462364

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM). User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 11:54:01 23 Sep 2020 19:11:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:52:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:52:37
Data point term sent to Coder	System	01 Sep 2020 00:51:38
User entered 'TOTAL HYSTERECTOMY'	(b) (4), (b) (6)	01 Sep 2020 00:51:32

US3462364

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:32

US3462364

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:32

US3462364

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:32

US3462364

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:32

US3462364

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:32

US3462364

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Jan 2004'	System	01 Sep 2020 00:51:32

US3462364

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '2004'	System	01 Sep 2020 00:51:32

US3462364

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Jan 2004'	System	01 Sep 2020 00:51:32

US3462364

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '2004'	System	01 Sep 2020 00:51:32

US3462364

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:53:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:53:39
Data point term sent to Coder	System	01 Sep 2020 00:52:38
User entered 'ANXIETY'	(b) (4), (b) (6)	01 Sep 2020 00:51:56

US3462364

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:56

US3462364

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:56

US3462364

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:56

US3462364

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:56

US3462364

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:51:56

US3462364

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Jan 2004'	System	01 Sep 2020 00:51:56

US3462364

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '2004'	System	01 Sep 2020 00:51:56

US3462364

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Sep 2020 00:51:56

US3462364

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Sep 2020 00:51:56

US3462364

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:53:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:53:38
Data point term sent to Coder	System	01 Sep 2020 00:52:39
User entered 'ALLERGY TO MORPHINE'	(b) (4), (b) (6)	01 Sep 2020 00:52:11

US3462364

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 1978'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:52:11

US3462364

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:52:11

US3462364

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
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	01 Sep 2020 00:52:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 00:52:32
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 00:52:11
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 00:52:11

US3462364

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:52:11

US3462364

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:52:11

US3462364

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Jan 1978'	System	01 Sep 2020 00:52:11

US3462364

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '1978'	System	01 Sep 2020 00:52:11

US3462364

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Sep 2020 00:52:11

US3462364

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Sep 2020 00:52:11

US3462364

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:53:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:53:39
Data point term sent to Coder	System	01 Sep 2020 00:52:39
User entered 'ALLERGY TO SULFA'	(b) (4), (b) (6)	01 Sep 2020 00:52:23

US3462364

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 1985'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:52:23

US3462364

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:52:23

US3462364

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:52:23

US3462364

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:52:23

US3462364

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:52:23

US3462364

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'Jan 1985'	System	01 Sep 2020 00:52:23

US3462364

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '1985'	System	01 Sep 2020 00:52:23

US3462364

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Sep 2020 00:52:23

US3462364

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Sep 2020 00:52:23

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered '11:38'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '27 Aug 2020 11:38'	System	01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered '167.6' cm	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:09
DataPoint set to visible.	System	27 Aug 2020 19:51:55

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered '90.7' kg	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:09
DataPoint set to visible.	System	27 Aug 2020 19:51:55

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '32.28935'	System	01 Sep 2020 00:54:09
DataPoint set to visible.	System	27 Aug 2020 19:51:55

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'kg/m2'	System	01 Sep 2020 00:54:09
DataPoint set to visible.	System	27 Aug 2020 19:51:55

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User closed query 'Per CDM: As per CCGs page 17-18, for Screening and Visit 1 on the same day, ND - 'Not Done'. should be recorded for Temperature (without unit), Pulse, Respiratory rate, Systolic BP and Diastolic BP. Please update accordingly. Note: Route of measurement should be left blank' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 08:36:25
Query 'Per CDM: As per CCGs page 17-18, for Screening and Visit 1 on the same day, ND - 'Not Done'. should be recorded for Temperature (without unit), Pulse, Respiratory rate, Systolic BP and Diastolic BP. Please update accordingly. Note: Route of measurement should be left blank' answered with 'Corrected' (Site from DM).		21 Jan 2021 01:12:03
User entered missing code ND - Not Done; reason for change Data Entry Error		21 Jan 2021 01:11:55
User opened query 'Per CDM: As per CCGs page 17-18, for Screening and Visit 1 on the same day, ND - 'Not Done'. should be recorded for Temperature (without unit), Pulse, Respiratory rate, Systolic BP and Diastolic BP. Please update accordingly. Note: Route of measurement should be left blank' (Site from DM).		28 Dec 2020 03:51:51
User entered '98.5' F		01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User closed query 'Per CDM re-query: Route of measurement and if Other, specify field can be left blank if the temperature is 'ND-NOT DONE'. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 07:07:07
Query 'Per CDM re-query: Route of measurement and if Other, specify field can be left blank if the temperature is 'ND-NOT DONE'. Please update accordingly. ' answered with 'Corrected' (Site from DM).		21 Jan 2021 18:10:13
User entered empty; reason for change Data Entry Error		21 Jan 2021 18:10:09
User opened query 'Per CDM re-query: Route of measurement and if Other, specify field can be left blank if the temperature is 'ND-NOT DONE'. Please update accordingly. ' (Site from DM).		21 Jan 2021 08:37:07
User entered 'Other (Other)'		01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User closed query 'Per CDM re-query: Please leave this field blank as it is not applicable when temperature is Not done. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 10:42:43
Query 'Per CDM re-query: Please leave this field blank as it is not applicable when temperature is Not done. ' answered with 'updated' (Site from DM).		04 Mar 2021 18:00:47
User entered empty; reason for change Data Entry Error		04 Mar 2021 18:00:35
User opened query 'Per CDM re-query: Please leave this field blank as it is not applicable when temperature is Not done. ' (Site from DM).		22 Jan 2021 07:07:05
User entered missing code ND - Not Done; reason for change Data Entry Error		21 Jan 2021 01:11:55
User entered 'TYMPANIC'		01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:11:55
User entered '84'		01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'bpm'	System	01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:11:55
User entered '20'		01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'breaths/min'	System	01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:11:55
User entered '148'		01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'mmHg'	System	01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:11:55
User entered '98'		01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'mmHg'	System	01 Sep 2020 00:54:09

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13

US3462364

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13

US3462364

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:20

US3462364

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:20

US3462364

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:51

US3462364

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:11

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:51

US3462364

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:11

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 12:14:48
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' answered with 'The medical condition is recorded in the medical history as the reason for the hysterectomy was the Ovarian Cyst in both ovaries.' (Site from DM).		04 Nov 2020 16:47:11
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).		09 Oct 2020 05:10:34
User entered 'Surgically sterile (SURGICALLY STERILE)'		01 Sep 2020 00:54:51

US3462364

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:11

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:51

US3462364

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:11

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:51

US3462364

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:11

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:51

US3462364

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:11

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:51

US3462364

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:11

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:54:51

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 23:04:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 23:04:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Aug 2020 23:35:44
User entered 'Yes (Y)'		27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Aug 2020 23:35:44
User entered 'No (N)'		27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Contact Tracing works for (b) (6)	(b) (4)	27 Aug 2020 23:35:44
(b) (6) reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 23:04:20
User entered empty.		

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'I'	(b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 23:04:20

US3462364

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 00:56:15

US3462364

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 00:56:15

US3462364

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:56:15

US3462364

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'VISIT1'	System	01 Sep 2020 00:56:15

US3462364

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:05:03

US3462364

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:11

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '188729'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:05:03

US3462364

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:05:03

US3462364

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:11

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)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 00:56:44

US3462364

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:11

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)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 00:56:44

US3462364

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:11

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 00:56:44

US3462364

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:11

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 00:56:44

US3462364

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 00:56:44

US3462364

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:11

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:53:08
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:48:12
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:18:37

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User closed query 'Per CDM: Please enter Not Done in the data field of the edc for Height.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 08:20:10
Query 'Per CDM: Please enter Not Done in the data field of the edc for Height.' answered with 'Updated' (Site from DM).		08 Nov 2020 15:33:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Nov 2020 15:32:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Nov 2020 15:32:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Nov 2020 15:32:20
User entered 'Not Done' (non-conformant).	(b) (4), (b) (6)	08 Nov 2020 15:32:20
User opened query 'Per CDM: Please enter Not Done in the data field of the edc for Height.' (Site from DM).		05 Nov 2020 20:18:38
Query 'Per CDM: Please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' canceled (Site from DM).		05 Nov 2020 20:18:20
User opened query 'Per CDM: Please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' (Site from DM).		05 Nov 2020 20:17:26
User closed query 'Per CDM: Response of 'Not Done' noted. However, please update data field to ND as per pg 15-16 of CCGs as data fields cannot be blank.' (Site from DM).		05 Nov 2020 20:16:43
Query 'Per CDM: Response of 'Not Done' noted. However, please update data field to ND as per pg 15-16 of CCGs as data fields cannot be blank.' answered with 'Updated' (Site from DM).		02 Nov 2020 22:38:45
User opened query 'Per CDM: Response of 'Not Done' noted. However, please update data field to ND as per pg 15-16 of CCGs as data fields cannot be blank.' (Site from DM).		27 Oct 2020 15:55:56

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Height

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	27 Oct 2020 15:55:56
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 'Not Done' (Site from DM).		22 Oct 2020 16:14:28
User entered empty; reason for change Data Entry Error		22 Oct 2020 16:14:13
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).		05 Oct 2020 15:35:47
User entered '167.6' cm		01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	System	08 Nov 2020 15:32:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	08 Nov 2020 15:32:58
User entered 'Not Done' (non-conformant).		
User closed query 'Per CDM: Per the CCGs, please record Weight as ND and uncheck the units.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 15:32:36
Query 'Per CDM: Per the CCGs, please record Weight as ND and uncheck the units.' answered with 'Updated' (Site from DM).		08 Nov 2020 15:32:36
User entered empty; reason for change Data Entry Error		05 Nov 2020 20:18:18
User opened query 'Per CDM: Per the CCGs, please record Weight as ND and uncheck the units.' (Site from DM).		02 Nov 2020 22:38:53
User entered '90.7' kg		02 Nov 2020 22:38:33
		02 Nov 2020 10:40:24
		01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User closed query 'Per CDM: Please enter Not Done in the data field of the edc for Height.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 08:20:10
Query 'Per CDM: Please enter Not Done in the data field of the edc for Height.' answered with 'Updated' (Site from DM).		08 Nov 2020 15:33:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Nov 2020 15:32:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Nov 2020 15:32:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Nov 2020 15:32:20
User entered 'Not Done' (non-conformant).	(b) (4), (b) (6)	08 Nov 2020 15:32:20
User opened query 'Per CDM: Please enter Not Done in the data field of the edc for Height.' (Site from DM).		05 Nov 2020 20:18:38
Query 'Per CDM: Please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' canceled (Site from DM).		05 Nov 2020 20:18:20
User opened query 'Per CDM: Please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' (Site from DM).		05 Nov 2020 20:17:26
User closed query 'Per CDM: Response of 'Not Done' noted. However, please update data field to ND as per pg 15-16 of CCGs as data fields cannot be blank.' (Site from DM).		05 Nov 2020 20:16:43
Query 'Per CDM: Response of 'Not Done' noted. However, please update data field to ND as per pg 15-16 of CCGs as data fields cannot be blank.' answered with 'Updated' (Site from DM).		02 Nov 2020 22:38:45
User opened query 'Per CDM: Response of 'Not Done' noted. However, please update data field to ND as per pg 15-16 of CCGs as data fields cannot be blank.' (Site from DM).		27 Oct 2020 15:55:56

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Height

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	27 Oct 2020 15:55:56
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 'Not Done' (Site from DM).		22 Oct 2020 16:14:28
User entered empty; reason for change Data Entry Error		22 Oct 2020 16:14:13
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).		05 Oct 2020 15:35:47
User entered '167.6' cm		01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	System	08 Nov 2020 15:32:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	08 Nov 2020 15:32:58
User entered 'Not Done' (non-conformant).		
User closed query 'Per CDM: Per the CCGs, please record Weight as ND and uncheck the units.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 15:32:36
Query 'Per CDM: Per the CCGs, please record Weight as ND and uncheck the units.' answered with 'Updated' (Site from DM).		08 Nov 2020 15:32:36
User entered empty; reason for change Data Entry Error		05 Nov 2020 20:18:18
User opened query 'Per CDM: Per the CCGs, please record Weight as ND and uncheck the units.' (Site from DM).		02 Nov 2020 22:38:53
User entered '90.7' kg		02 Nov 2020 22:38:33
		02 Nov 2020 10:40:24
		01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User accepted default value 'Pre-Dose (PREDOSE)'		01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '11:38'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '27 Aug 2020 11:38'	System	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '98.5' F	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Other (Other)'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'TYMPANIC'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '84'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'bpm'	System	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '20'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'breaths/min'	System	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '148'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'mmHg'	System	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '98'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'mmHg'	System	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User closed query 'Per CDM: Please enter Not Done in the data field of the edc for Height.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 08:20:10
Query 'Per CDM: Please enter Not Done in the data field of the edc for Height.' answered with 'Updated' (Site from DM).		08 Nov 2020 15:33:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Nov 2020 15:32:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Nov 2020 15:32:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Nov 2020 15:32:20
User entered 'Not Done' (non-conformant).	(b) (4), (b) (6)	08 Nov 2020 15:32:20
User opened query 'Per CDM: Please enter Not Done in the data field of the edc for Height.' (Site from DM).		05 Nov 2020 20:18:38
Query 'Per CDM: Please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' canceled (Site from DM).		05 Nov 2020 20:18:20
User opened query 'Per CDM: Please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' (Site from DM).		05 Nov 2020 20:17:26
User closed query 'Per CDM: Response of 'Not Done' noted. However, please update data field to ND as per pg 15-16 of CCGs as data fields cannot be blank.' (Site from DM).		05 Nov 2020 20:16:43
Query 'Per CDM: Response of 'Not Done' noted. However, please update data field to ND as per pg 15-16 of CCGs as data fields cannot be blank.' answered with 'Updated' (Site from DM).		02 Nov 2020 22:38:45
User opened query 'Per CDM: Response of 'Not Done' noted. However, please update data field to ND as per pg 15-16 of CCGs as data fields cannot be blank.' (Site from DM).		27 Oct 2020 15:55:56

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Height

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	27 Oct 2020 15:55:56
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 'Not Done' (Site from DM).		22 Oct 2020 16:14:28
User entered empty; reason for change Data Entry Error		22 Oct 2020 16:14:13
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).		05 Oct 2020 15:35:47
User entered '167.6' cm		01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	System	08 Nov 2020 15:32:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	08 Nov 2020 15:32:58
User entered 'Not Done' (non-conformant).		
User closed query 'Per CDM: Per the CCGs, please record Weight as ND and uncheck the units.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 15:32:36
Query 'Per CDM: Per the CCGs, please record Weight as ND and uncheck the units.' answered with 'Updated' (Site from DM).		08 Nov 2020 15:32:36
User entered empty; reason for change Data Entry Error		05 Nov 2020 20:18:18
User opened query 'Per CDM: Per the CCGs, please record Weight as ND and uncheck the units.' (Site from DM).		02 Nov 2020 22:38:53
User entered '90.7' kg		02 Nov 2020 22:38:33
		02 Nov 2020 10:40:24
		01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User accepted default value 'Post-Dose (POSTDOSE)'		01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '13:03'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '27 Aug 2020 13:03'	System	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '98.2' F	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Other (Other)'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'TYMPANIC'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '75'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'bpm'	System	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '16'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'breaths/min'	System	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '132'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'mmHg'	System	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '89'	(b) (4), (b) (6)	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'mmHg'	System	01 Sep 2020 00:58:17

US3462364

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:58:47

US3462364

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 00:58:47

US3462364

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:52:30

US3462364

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:52:30

US3462364

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:52:30

US3462364

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 19:52:30

US3462364

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:52:30

US3462364

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '12:33'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:52:30

US3462364

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '27 Aug 2020 12:33'	System	27 Aug 2020 19:52:30

US3462364

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:52:30

US3462364

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'ONCE'	System	27 Aug 2020 19:52:30

US3462364

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 19:52:30

US3462364

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 00:59:30

US3462364

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 00:59:30

US3462364

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '12:27'	(b) (4), (b) (6)	01 Sep 2020 00:59:30

US3462364

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '27 Aug 2020 12:27'	System	01 Sep 2020 00:59:30

US3462364

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '27 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 00:59:56

US3462364

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		01 Sep 2020 00:59:56

US3462364

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 00:59:56

US3462364

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '12:27'	(b) (4), (b) (6)	01 Sep 2020 00:59:56

US3462364

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '27 Aug 2020 12:27'	System	01 Sep 2020 00:59:56

US3462364

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		01 Sep 2020 00:59:56

US3462364

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:53:24
User entered 'Yes (Y)'		01 Sep 2020 00:59:56

US3462364

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:53:24
User entered '12:27'		01 Sep 2020 00:59:56

US3462364

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered empty.	System	13 Oct 2020 00:53:24
User entered '27 Aug 2020 12:27'	System	01 Sep 2020 00:59:56

US3462364

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:00:02

US3462364

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'I'	System	01 Sep 2020 01:00:02

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:03:36', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1d94a7bd-beff-4f73-a910-3080bd4b788f' User entered 'Yes (Y)'	System	27 Aug 2020 20:04:07
	System	27 Aug 2020 20:04:07

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:03:42', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1d94a7bd-beff-4f73-a910-3080bd4b788f' User entered '98.2'	System	27 Aug 2020 20:04:07
	System	27 Aug 2020 20:04:07

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:03:48', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1d94a7bd-beff-4f73-a910-3080bd4b788f'	System	27 Aug 2020 20:04:07
User entered 'No (N)'	System	27 Aug 2020 20:04:07

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:04:03', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1d94a7bd-beff-4f73-a910-3080bd4b788f' User entered '27 Aug 2020 13:04'	System	27 Aug 2020 20:04:07
	System	27 Aug 2020 20:04:07

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Aug 2020 12:53'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Aug 2020 15:23'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:06:54', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b68a7621-abb0-464b-8978-6060346093ae' User entered 'Yes (Y)'	System	28 Aug 2020 02:07:17
	System	28 Aug 2020 02:07:17

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:02', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b68a7621-abb0-464b-8978-6060346093ae' User entered '97.9'	System	28 Aug 2020 02:07:17
	System	28 Aug 2020 02:07:17

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:07', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b68a7621-abb0-464b-8978-6060346093ae' User entered 'No (N)'	System	28 Aug 2020 02:07:17
	System	28 Aug 2020 02:07:17

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:13', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b68a7621-abb0-464b-8978-6060346093ae'	System	28 Aug 2020 02:07:17
User entered '27 Aug 2020 19:07'	System	28 Aug 2020 02:07:17

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Aug 2020 16:18'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 2'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:09:50', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'db69acc6-e117-4ce4-96dc-527283d41381' User entered 'Yes (Y)'	System	29 Aug 2020 02:10:17
	System	29 Aug 2020 02:10:17

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:09:57', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'db69acc6-e117-4ce4-96dc-527283d41381' User entered '98.3'	System	29 Aug 2020 02:10:17
	System	29 Aug 2020 02:10:17

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:10:01', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'db69acc6-e117-4ce4-96dc-527283d41381'	System	29 Aug 2020 02:10:17
User entered 'No (N)'	System	29 Aug 2020 02:10:17

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:10:12', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'db69acc6-e117-4ce4-96dc-527283d41381'	System	29 Aug 2020 02:10:17
User entered '28 Aug 2020 19:10'	System	29 Aug 2020 02:10:17

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 3'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:02:18', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '36ab9d20-1b20-4959-8838-dfedfde2bad1' User entered 'Yes (Y)'	System	30 Aug 2020 02:02:54
	System	30 Aug 2020 02:02:54

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:02:24', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '36ab9d20-1b20-4959-8838-dfedfde2bad1' User entered '97.5'	System	30 Aug 2020 02:02:54
	System	30 Aug 2020 02:02:54

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:02:33', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '36ab9d20-1b20-4959-8838-dfedfde2bad1'	System	30 Aug 2020 02:02:54
User entered 'Yes (Y)'	System	30 Aug 2020 02:02:54

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
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 'Conmed updated' (Site from System).		13 Nov 2020 12:13:00
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:02:40', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '36ab9d20-1b20-4959-8838-dfedfde2bad1'	System	30 Aug 2020 02:02:54
User entered '1'	System	30 Aug 2020 02:02:54

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:02:40', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '36ab9d20-1b20-4959-8838-dfedfde2bad1' User entered '0'	System	30 Aug 2020 02:02:54
	System	30 Aug 2020 02:02:54

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:02:52', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '36ab9d20-1b20-4959-8838-dfedfde2bad1'	System	30 Aug 2020 02:02:54
User entered '29 Aug 2020 19:02'	System	30 Aug 2020 02:02:54

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 4'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:01:30', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '93ca1b5b-7b67-4573-857f-51afa3fb97ea'	System	31 Aug 2020 02:01:59
User entered 'Yes (Y)'	System	31 Aug 2020 02:01:59

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:01:36', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '93ca1b5b-7b67-4573-857f-51afa3fb97ea' User entered '97.4'	System	31 Aug 2020 02:01:59
	System	31 Aug 2020 02:01:59

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:01:41', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '93ca1b5b-7b67-4573-857f-51afa3fb97ea'	System	31 Aug 2020 02:01:59
User entered 'Yes (Y)'	System	31 Aug 2020 02:01:59

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
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 'Conmed updated' (Site from System).		13 Nov 2020 12:13:05
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	31 Aug 2020 02:01:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:01:48', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '93ca1b5b-7b67-4573-857f-51afa3fb97ea'	System	31 Aug 2020 02:01:59
User entered '1'	System	31 Aug 2020 02:01:59

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:01:48', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '93ca1b5b-7b67-4573-857f-51afa3fb97ea' User entered '0'	System	31 Aug 2020 02:01:59
	System	31 Aug 2020 02:01:59

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:01:54', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '93ca1b5b-7b67-4573-857f-51afa3fb97ea'	System	31 Aug 2020 02:01:59
User entered '30 Aug 2020 19:01'	System	31 Aug 2020 02:01:59

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 5'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:19:28', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '7055870a-d965-4e18-9648-22379b1b845d' User entered 'Yes (Y)'	System	01 Sep 2020 02:19:46
	System	01 Sep 2020 02:19:46

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:19:33', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '7055870a-d965-4e18-9648-22379b1b845d' User entered '97.5'	System	01 Sep 2020 02:19:46
	System	01 Sep 2020 02:19:46

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:19:39', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '7055870a-d965-4e18-9648-22379b1b845d'	System	01 Sep 2020 02:19:46
User entered 'No (N)'	System	01 Sep 2020 02:19:46

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:19:44', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '7055870a-d965-4e18-9648-22379b1b845d' User entered '31 Aug 2020 19:19'	System	01 Sep 2020 02:19:46
	System	01 Sep 2020 02:19:46

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 6'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:28:07', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '75741e65-8b07-4d5d-b5a3-c322ab28ded0' User entered 'Yes (Y)'	System	02 Sep 2020 05:28:33
	System	02 Sep 2020 05:28:33

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:28:12', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '75741e65-8b07-4d5d-b5a3-c322ab28ded0' User entered '97.6'	System	02 Sep 2020 05:28:33
	System	02 Sep 2020 05:28:33

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:28:26', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '75741e65-8b07-4d5d-b5a3-c322ab28ded0' User entered 'No (N)'	System	02 Sep 2020 05:28:33
	System	02 Sep 2020 05:28:33

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:28:31', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '75741e65-8b07-4d5d-b5a3-c322ab28ded0'	System	02 Sep 2020 05:28:33
User entered '01 Sep 2020 22:28'	System	02 Sep 2020 05:28:33

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 7'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:58:18', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bcb65c99-badf-4bc3-9a9c-8899c7a6ee66'	System	03 Sep 2020 01:59:04
User entered 'Yes (Y)'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:58:26', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bcb65c99-badf-4bc3-9a9c-8899c7a6ee66'	System	03 Sep 2020 01:59:04
User entered '96.7'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:58:31', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bcb65c99-badf-4bc3-9a9c-8899c7a6ee66'	System	03 Sep 2020 01:59:04
User entered 'Yes (Y)'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
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 'Conmed updated' (Site from System).		13 Nov 2020 12:13:15
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	04 Nov 2020 16:44:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:58:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bcb65c99-badf-4bc3-9a9c-8899c7a6ee66'	System	03 Sep 2020 01:59:04
User entered '1'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:58:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bcb65c99-badf-4bc3-9a9c-8899c7a6ee66'	System	03 Sep 2020 01:59:04
User entered '0'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:59:02', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bcb65c99-badf-4bc3-9a9c-8899c7a6ee66'	System	03 Sep 2020 01:59:04
User entered '02 Sep 2020 18:59'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	03 Sep 2020 01:59:04
User entered 'Day 8'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-03T19:00:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '71c2da32-7714-4317-ac30-c070770cd257'	System	04 Sep 2020 02:01:18
User entered 'Yes (Y)'	System	04 Sep 2020 02:01:18

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-03T19:00:59', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '71c2da32-7714-4317-ac30-c070770cd257' User entered '98.1'	System	04 Sep 2020 02:01:18
	System	04 Sep 2020 02:01:18

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-03T19:01:03', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '71c2da32-7714-4317-ac30-c070770cd257'	System	04 Sep 2020 02:01:18
User entered 'No (N)'	System	04 Sep 2020 02:01:18

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-03T19:01:13', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '71c2da32-7714-4317-ac30-c070770cd257'	System	04 Sep 2020 02:01:18
User entered '03 Sep 2020 19:01'	System	04 Sep 2020 02:01:18

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '03 Sep 2020 12:00'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:04:10', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bacd5158-989c-43ae-b7aa-646672c667f4' User entered 'None (1)'	System	27 Aug 2020 20:04:42
	System	27 Aug 2020 20:04:42

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:04:22', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bacd5158-989c-43ae-b7aa-646672c667f4'	System	27 Aug 2020 20:04:42
User entered 'No (N)'	System	27 Aug 2020 20:04:42

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:04:28', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bacd5158-989c-43ae-b7aa-646672c667f4'	System	27 Aug 2020 20:04:42
User entered 'No (N)'	System	27 Aug 2020 20:04:42

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:04:34', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bacd5158-989c-43ae-b7aa-646672c667f4' User entered 'None (1)'	System	27 Aug 2020 20:04:42
	System	27 Aug 2020 20:04:42

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:04:39', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'bacd5158-989c-43ae-b7aa-646672c667f4'	System	27 Aug 2020 20:04:42
User entered '27 Aug 2020 13:04'	System	27 Aug 2020 20:04:42

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Aug 2020 12:53'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Aug 2020 15:23'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:19', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '22bad6ca-3bcb-488d-ab94-8bea2e8b47bb' User entered 'None (1)'	System	28 Aug 2020 02:07:41
	System	28 Aug 2020 02:07:41

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:22', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '22bad6ca-3bcb-488d-ab94-8bea2e8b47bb' User entered 'No (N)'	System	28 Aug 2020 02:07:41
	System	28 Aug 2020 02:07:41

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:25', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '22bad6ca-3bcb-488d-ab94-8bea2e8b47bb' User entered 'No (N)'	System	28 Aug 2020 02:07:41
	System	28 Aug 2020 02:07:41

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:29', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '22bad6ca-3bcb-488d-ab94-8bea2e8b47bb' User entered 'None (1)'	System	28 Aug 2020 02:07:41
	System	28 Aug 2020 02:07:41

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:37', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '22bad6ca-3bcb-488d-ab94-8bea2e8b47bb' User entered '27 Aug 2020 19:07'	System	28 Aug 2020 02:07:41
	System	28 Aug 2020 02:07:41

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Aug 2020 16:18'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 2'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:09:07', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'fbb768c2-d857-4224-a147-b56e333729c0' User entered 'None (1)'	System	29 Aug 2020 02:09:45
	System	29 Aug 2020 02:09:45

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:09:12', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'fbb768c2-d857-4224-a147-b56e333729c0'	System	29 Aug 2020 02:09:45
User entered 'No (N)'	System	29 Aug 2020 02:09:45

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:09:16', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'fbb768c2-d857-4224-a147-b56e333729c0' User entered 'No (N)'	System	29 Aug 2020 02:09:45
	System	29 Aug 2020 02:09:45

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:09:20', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'fbb768c2-d857-4224-a147-b56e333729c0' User entered 'None (1)'	System	29 Aug 2020 02:09:45
	System	29 Aug 2020 02:09:45

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:09:41', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'fbb768c2-d857-4224-a147-b56e333729c0' User entered '28 Aug 2020 19:09'	System	29 Aug 2020 02:09:45
	System	29 Aug 2020 02:09:45

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 3'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:02:59', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b203635b-8946-490a-a8af-2a3f1c558e73' User entered 'None (1)'	System	30 Aug 2020 02:03:22
	System	30 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:03:02', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b203635b-8946-490a-a8af-2a3f1c558e73'	System	30 Aug 2020 02:03:22
User entered 'No (N)'	System	30 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:03:06', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b203635b-8946-490a-a8af-2a3f1c558e73'	System	30 Aug 2020 02:03:22
User entered 'No (N)'	System	30 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:03:10', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b203635b-8946-490a-a8af-2a3f1c558e73' User entered 'None (1)'	System	30 Aug 2020 02:03:22
	System	30 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:03:18', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b203635b-8946-490a-a8af-2a3f1c558e73'	System	30 Aug 2020 02:03:22
User entered '29 Aug 2020 19:03'	System	30 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 4'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:02:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e86800a4-c27d-470e-ac0b-b7a47340a4c5'	System	31 Aug 2020 02:02:18
User entered 'None (1)'	System	31 Aug 2020 02:02:18

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:02:05', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e86800a4-c27d-470e-ac0b-b7a47340a4c5'	System	31 Aug 2020 02:02:18
User entered 'No (N)'	System	31 Aug 2020 02:02:18

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:02:08', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e86800a4-c27d-470e-ac0b-b7a47340a4c5'	System	31 Aug 2020 02:02:18
User entered 'No (N)'	System	31 Aug 2020 02:02:18

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:02:12', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e86800a4-c27d-470e-ac0b-b7a47340a4c5'	System	31 Aug 2020 02:02:18
User entered 'None (1)'	System	31 Aug 2020 02:02:18

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:02:15', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e86800a4-c27d-470e-ac0b-b7a47340a4c5'	System	31 Aug 2020 02:02:18
User entered '30 Aug 2020 19:02'	System	31 Aug 2020 02:02:18

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 5'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:19:50', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '3a8bc862-4846-4306-88dc-391e110ddef6' User entered 'None (1)'	System	01 Sep 2020 02:20:05
	System	01 Sep 2020 02:20:05

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:19:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '3a8bc862-4846-4306-88dc-391e110ddef6' User entered 'No (N)'	System	01 Sep 2020 02:20:05
	System	01 Sep 2020 02:20:05

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:19:56', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '3a8bc862-4846-4306-88dc-391e110ddef6'	System	01 Sep 2020 02:20:05
User entered 'No (N)'	System	01 Sep 2020 02:20:05

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:19:59', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '3a8bc862-4846-4306-88dc-391e110ddef6' User entered 'None (1)'	System	01 Sep 2020 02:20:05
	System	01 Sep 2020 02:20:05

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:20:02', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '3a8bc862-4846-4306-88dc-391e110ddef6'	System	01 Sep 2020 02:20:05
User entered '31 Aug 2020 19:20'	System	01 Sep 2020 02:20:05

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 6'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:28:37', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f0f944ef-91f5-4993-ac1a-4fd3ecf15886'	System	02 Sep 2020 05:28:55
User entered 'None (1)'	System	02 Sep 2020 05:28:55

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:28:41', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f0f944ef-91f5-4993-ac1a-4fd3ecf15886'	System	02 Sep 2020 05:28:55
User entered 'No (N)'	System	02 Sep 2020 05:28:55

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:28:44', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f0f944ef-91f5-4993-ac1a-4fd3ecf15886'	System	02 Sep 2020 05:28:55
User entered 'No (N)'	System	02 Sep 2020 05:28:55

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:28:48', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f0f944ef-91f5-4993-ac1a-4fd3ecf15886' User entered 'None (1)'	System	02 Sep 2020 05:28:55
	System	02 Sep 2020 05:28:55

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:28:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f0f944ef-91f5-4993-ac1a-4fd3ecf15886'	System	02 Sep 2020 05:28:55
User entered '01 Sep 2020 22:28'	System	02 Sep 2020 05:28:55

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 7'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:59:08', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b5819236-c517-4fb1-ab54-93f538d6b9ae' User entered 'None (1)'	System	03 Sep 2020 01:59:26
	System	03 Sep 2020 01:59:26

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:59:11', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b5819236-c517-4fb1-ab54-93f538d6b9ae'	System	03 Sep 2020 01:59:26
User entered 'No (N)'	System	03 Sep 2020 01:59:26

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:59:17', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b5819236-c517-4fb1-ab54-93f538d6b9ae'	System	03 Sep 2020 01:59:26
User entered 'No (N)'	System	03 Sep 2020 01:59:26

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:59:21', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b5819236-c517-4fb1-ab54-93f538d6b9ae' User entered 'None (1)'	System	03 Sep 2020 01:59:26
	System	03 Sep 2020 01:59:26

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:59:24', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b5819236-c517-4fb1-ab54-93f538d6b9ae'	System	03 Sep 2020 01:59:26
User entered '02 Sep 2020 18:59'	System	03 Sep 2020 01:59:26

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:04:54', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2938bbcf-bf66-4d86-a136-b978d12ec547'	System	27 Aug 2020 20:05:21
User entered 'None (0)'	System	27 Aug 2020 20:05:21

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:04:57', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2938bbcf-bf66-4d86-a136-b978d12ec547'	System	27 Aug 2020 20:05:21
User entered 'None (0)'	System	27 Aug 2020 20:05:21

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:05:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2938bbcf-bf66-4d86-a136-b978d12ec547'	System	27 Aug 2020 20:05:21
User entered 'None (0)'	System	27 Aug 2020 20:05:21

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:05:02', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2938bbcf-bf66-4d86-a136-b978d12ec547'	System	27 Aug 2020 20:05:21
User entered 'None (0)'	System	27 Aug 2020 20:05:21

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:05:05', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2938bbcf-bf66-4d86-a136-b978d12ec547'	System	27 Aug 2020 20:05:21
User entered 'None (0)'	System	27 Aug 2020 20:05:21

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:05:08', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2938bbcf-bf66-4d86-a136-b978d12ec547'	System	27 Aug 2020 20:05:21
User entered 'None (0)'	System	27 Aug 2020 20:05:21

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:05:13', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2938bbcf-bf66-4d86-a136-b978d12ec547'	System	27 Aug 2020 20:05:21
User entered 'No (N)'	System	27 Aug 2020 20:05:21

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T13:05:19', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2938bbcf-bf66-4d86-a136-b978d12ec547'	System	27 Aug 2020 20:05:21
User entered '27 Aug 2020 13:05'	System	27 Aug 2020 20:05:21

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Aug 2020 12:53'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Aug 2020 15:23'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:42', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e3fe57dd-ecb2-46e1-b3c2-f780a2929029'	System	28 Aug 2020 02:08:24
User entered 'None (0)'	System	28 Aug 2020 02:08:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:50', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e3fe57dd-ecb2-46e1-b3c2-f780a2929029'	System	28 Aug 2020 02:08:24
User entered 'No interference with activity (1)'	System	28 Aug 2020 02:08:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:54', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e3fe57dd-ecb2-46e1-b3c2-f780a2929029' User entered 'None (0)'	System	28 Aug 2020 02:08:24
	System	28 Aug 2020 02:08:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:07:57', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e3fe57dd-ecb2-46e1-b3c2-f780a2929029' User entered 'None (0)'	System	28 Aug 2020 02:08:24
	System	28 Aug 2020 02:08:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:08:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e3fe57dd-ecb2-46e1-b3c2-f780a2929029' User entered 'None (0)'	System	28 Aug 2020 02:08:24
	System	28 Aug 2020 02:08:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:08:02', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e3fe57dd-ecb2-46e1-b3c2-f780a2929029'	System	28 Aug 2020 02:08:24
User entered 'None (0)'	System	28 Aug 2020 02:08:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:08:10', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e3fe57dd-ecb2-46e1-b3c2-f780a2929029'	System	28 Aug 2020 02:08:24
User entered 'No (N)'	System	28 Aug 2020 02:08:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-27T19:08:20', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e3fe57dd-ecb2-46e1-b3c2-f780a2929029' User entered '27 Aug 2020 19:08'	System	28 Aug 2020 02:08:24
	System	28 Aug 2020 02:08:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Aug 2020 16:18'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 2'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:10:17', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4e89446b-2926-405b-b45d-adf99da8f33d'	System	29 Aug 2020 02:10:54
User entered 'None (0)'	System	29 Aug 2020 02:10:54

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:10:21', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4e89446b-2926-405b-b45d-adf99da8f33d'	System	29 Aug 2020 02:10:54
User entered 'No interference with activity (1)'	System	29 Aug 2020 02:10:54

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:10:24', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4e89446b-2926-405b-b45d-adf99da8f33d' User entered 'None (0)'	System	29 Aug 2020 02:10:54
	System	29 Aug 2020 02:10:54

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:10:33', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4e89446b-2926-405b-b45d-adf99da8f33d' User entered 'None (0)'	System	29 Aug 2020 02:10:54
	System	29 Aug 2020 02:10:54

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:10:36', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4e89446b-2926-405b-b45d-adf99da8f33d' User entered 'None (0)'	System	29 Aug 2020 02:10:54
	System	29 Aug 2020 02:10:54

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:10:38', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4e89446b-2926-405b-b45d-adf99da8f33d' User entered 'None (0)'	System	29 Aug 2020 02:10:54
	System	29 Aug 2020 02:10:54

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:10:42', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4e89446b-2926-405b-b45d-adf99da8f33d'	System	29 Aug 2020 02:10:54
User entered 'No (N)'	System	29 Aug 2020 02:10:54

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-28T19:10:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4e89446b-2926-405b-b45d-adf99da8f33d' User entered '28 Aug 2020 19:10'	System	29 Aug 2020 02:10:54
	System	29 Aug 2020 02:10:54

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 3'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:03:38', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '95f727bb-3cc9-41bb-9ff0-012601cec3dd'	System	30 Aug 2020 02:04:26
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		30 Aug 2020 02:04:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:03:45', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '95f727bb-3cc9-41bb-9ff0-012601cec3dd' User entered 'None (0)'	System	30 Aug 2020 02:04:26
	System	30 Aug 2020 02:04:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:03:49', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '95f727bb-3cc9-41bb-9ff0-012601cec3dd' User entered 'None (0)'	System	30 Aug 2020 02:04:26
	System	30 Aug 2020 02:04:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:03:52', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '95f727bb-3cc9-41bb-9ff0-012601cec3dd' User entered 'None (0)'	System	30 Aug 2020 02:04:26
	System	30 Aug 2020 02:04:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:03:56', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '95f727bb-3cc9-41bb-9ff0-012601cec3dd' User entered 'None (0)'	System	30 Aug 2020 02:04:26
	System	30 Aug 2020 02:04:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:04:02', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '95f727bb-3cc9-41bb-9ff0-012601cec3dd' User entered 'None (0)'	System	30 Aug 2020 02:04:26
	System	30 Aug 2020 02:04:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:04:11', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '95f727bb-3cc9-41bb-9ff0-012601cec3dd'	System	30 Aug 2020 02:04:26
User entered 'No (N)'	System	30 Aug 2020 02:04:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-29T19:04:23', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '95f727bb-3cc9-41bb-9ff0-012601cec3dd' User entered '29 Aug 2020 19:04'	System	30 Aug 2020 02:04:26
	System	30 Aug 2020 02:04:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 4'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:02:30', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd432b571-6c05-4327-9307-d164d9cd3a8f'	System	31 Aug 2020 02:03:22
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	31 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:02:38', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd432b571-6c05-4327-9307-d164d9cd3a8f'	System	31 Aug 2020 02:03:22
User entered 'Some interference with activity (2)'	System	31 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:02:47', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd432b571-6c05-4327-9307-d164d9cd3a8f'	System	31 Aug 2020 02:03:22
User entered 'None (0)'	System	31 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:02:52', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd432b571-6c05-4327-9307-d164d9cd3a8f' User entered 'None (0)'	System	31 Aug 2020 02:03:22
	System	31 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:02:55', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd432b571-6c05-4327-9307-d164d9cd3a8f'	System	31 Aug 2020 02:03:22
User entered 'None (0)'	System	31 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:03:03', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd432b571-6c05-4327-9307-d164d9cd3a8f'	System	31 Aug 2020 02:03:22
User entered 'None (0)'	System	31 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:03:09', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd432b571-6c05-4327-9307-d164d9cd3a8f'	System	31 Aug 2020 02:03:22
User entered 'No (N)'	System	31 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-30T19:03:18', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd432b571-6c05-4327-9307-d164d9cd3a8f' User entered '30 Aug 2020 19:03'	System	31 Aug 2020 02:03:22
	System	31 Aug 2020 02:03:22

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 5'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:20:10', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f100ed2f-9151-4f4b-a479-d3ab09ffa1c0' User entered 'None (0)'	System	01 Sep 2020 02:20:34
	System	01 Sep 2020 02:20:34

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:20:13', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f100ed2f-9151-4f4b-a479-d3ab09ffa1c0'	System	01 Sep 2020 02:20:34
User entered 'None (0)'	System	01 Sep 2020 02:20:34

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:20:16', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f100ed2f-9151-4f4b-a479-d3ab09ffa1c0'	System	01 Sep 2020 02:20:34
User entered 'None (0)'	System	01 Sep 2020 02:20:34

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:20:18', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f100ed2f-9151-4f4b-a479-d3ab09ffa1c0'	System	01 Sep 2020 02:20:34
User entered 'None (0)'	System	01 Sep 2020 02:20:34

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:20:21', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f100ed2f-9151-4f4b-a479-d3ab09ffa1c0'	System	01 Sep 2020 02:20:34
User entered 'None (0)'	System	01 Sep 2020 02:20:34

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:20:24', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f100ed2f-9151-4f4b-a479-d3ab09ffa1c0'	System	01 Sep 2020 02:20:34
User entered 'None (0)'	System	01 Sep 2020 02:20:34

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:20:28', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f100ed2f-9151-4f4b-a479-d3ab09ffa1c0'	System	01 Sep 2020 02:20:34
User entered 'No (N)'	System	01 Sep 2020 02:20:34

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-08-31T19:20:31', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f100ed2f-9151-4f4b-a479-d3ab09ffa1c0'	System	01 Sep 2020 02:20:34
User entered '31 Aug 2020 19:20'	System	01 Sep 2020 02:20:34

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 6'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:28:58', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4a31b268-b73a-47bf-8c16-45c13f80fdbb' User entered 'None (0)'	System	02 Sep 2020 05:29:24
	System	02 Sep 2020 05:29:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:29:01', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4a31b268-b73a-47bf-8c16-45c13f80fdbb' User entered 'None (0)'	System	02 Sep 2020 05:29:24
	System	02 Sep 2020 05:29:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:29:04', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4a31b268-b73a-47bf-8c16-45c13f80fdbb' User entered 'None (0)'	System	02 Sep 2020 05:29:24
	System	02 Sep 2020 05:29:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:29:07', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4a31b268-b73a-47bf-8c16-45c13f80fdbb' User entered 'None (0)'	System	02 Sep 2020 05:29:24
	System	02 Sep 2020 05:29:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:29:10', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4a31b268-b73a-47bf-8c16-45c13f80fdbb' User entered 'None (0)'	System	02 Sep 2020 05:29:24
	System	02 Sep 2020 05:29:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:29:12', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4a31b268-b73a-47bf-8c16-45c13f80fdbb' User entered 'None (0)'	System	02 Sep 2020 05:29:24
	System	02 Sep 2020 05:29:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:29:17', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4a31b268-b73a-47bf-8c16-45c13f80fdbb'	System	02 Sep 2020 05:29:24
User entered 'No (N)'	System	02 Sep 2020 05:29:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-01T22:29:22', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4a31b268-b73a-47bf-8c16-45c13f80fdbb'	System	02 Sep 2020 05:29:24
User entered '01 Sep 2020 22:29'	System	02 Sep 2020 05:29:24

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 7'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:59:40', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '53fbf4ef-d7a8-4d74-81c8-77a8c98e256f'	System	03 Sep 2020 02:00:26
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:59:46', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '53fbf4ef-d7a8-4d74-81c8-77a8c98e256f'	System	03 Sep 2020 02:00:26
User entered 'Some interference with activity (2)'	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:59:50', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '53fbf4ef-d7a8-4d74-81c8-77a8c98e256f' User entered 'None (0)'	System	03 Sep 2020 02:00:26
	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T18:59:55', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '53fbf4ef-d7a8-4d74-81c8-77a8c98e256f' User entered 'None (0)'	System	03 Sep 2020 02:00:26
	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T19:00:03', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '53fbf4ef-d7a8-4d74-81c8-77a8c98e256f' User entered 'None (0)'	System	03 Sep 2020 02:00:26
	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T19:00:06', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '53fbf4ef-d7a8-4d74-81c8-77a8c98e256f' User entered 'None (0)'	System	03 Sep 2020 02:00:26
	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T19:00:10', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '53fbf4ef-d7a8-4d74-81c8-77a8c98e256f'	System	03 Sep 2020 02:00:26
User entered 'No (N)'	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-02T19:00:23', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '53fbf4ef-d7a8-4d74-81c8-77a8c98e256f'	System	03 Sep 2020 02:00:26
User entered '02 Sep 2020 19:00'	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	03 Sep 2020 02:00:26
User entered 'Day 8'	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:40:11

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-03T19:01:20', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '5b23ac9b-4ac6-4cb7-adac-e46a6a13a718' User entered 'None (0)'	System	04 Sep 2020 02:01:25
	System	04 Sep 2020 02:01:25

US3462364

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-03T19:01:24', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '5b23ac9b-4ac6-4cb7-adac-e46a6a13a718' User entered '03 Sep 2020 19:01'	System	04 Sep 2020 02:01:25
	System	04 Sep 2020 02:01:25

US3462364

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '03 Sep 2020 12:00'	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	03 Sep 2020 02:00:26
User entered 'Day 8'	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:40:11

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-03T19:01:29', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'c351b57b-5a0c-491c-bce5-41a624495a42' User entered 'None (0)'	System	04 Sep 2020 02:01:37
	System	04 Sep 2020 02:01:37

US3462364

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-03T19:01:31', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'c351b57b-5a0c-491c-bce5-41a624495a42'	System	04 Sep 2020 02:01:37
User entered '03 Sep 2020 19:01'	System	04 Sep 2020 02:01:37

US3462364

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '03 Sep 2020 12:00'	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 02:00:26

US3462364

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	03 Sep 2020 01:59:04
User entered 'Day 8'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-03T19:01:36', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '737d51d8-b00c-4e88-aa9a-a24608389bd2'	System	04 Sep 2020 02:01:41
User entered 'No (N)'	System	04 Sep 2020 02:01:41

US3462364

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-03T19:01:39', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '737d51d8-b00c-4e88-aa9a-a24608389bd2'	System	04 Sep 2020 02:01:41
User entered '03 Sep 2020 19:01'	System	04 Sep 2020 02:01:41

US3462364

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '03 Sep 2020 12:00'	System	03 Sep 2020 01:59:04

US3462364

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 01:59:04

US3462364

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:11:09

US3462364

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	11 Sep 2020 18:13:46
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).		11 Sep 2020 18:13:46
User entered '3 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:13:46
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Sep 2020 18:11:09
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3462364

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:11:09

US3462364

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3462364

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:13:54

US3462364

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'I'	System	11 Sep 2020 18:13:54

US3462364

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:58:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:14:08

US3462364

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:58:38
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:14:08

US3462364

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:58:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:14:08

US3462364

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:58:38
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:14:08

US3462364

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:58:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:35:30

US3462364

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'I'	System	17 Sep 2020 19:35:30

US3462364

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:35:43

US3462364

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:35:43

US3462364

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:35:43

US3462364

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:35:43

US3462364

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:58:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:41:03

US3462364

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'I'	System	24 Sep 2020 17:41:03

US3462364

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:41:15

US3462364

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 17:41:15

US3462364

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:41:15

US3462364

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'VISIT2'	System	24 Sep 2020 17:41:15

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User accepted default value 'Pre-Dose (PREDOSE)'		24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '10:01'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '24 Sep 2020 10:01'	System	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '98.3' F	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'tympanic'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '79'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'bpm'	System	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '18'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'breaths/min'	System	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '132'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'mmHg'	System	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '93'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'mmHg'	System	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User accepted default value 'Post-Dose (POSTDOSE)'		24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '10:57'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '24 Sep 2020 10:57'	System	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '98.4' F	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'tympanic'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '96'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'bpm'	System	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'breaths/min'	System	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '128'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'mmHg'	System	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '92'	(b) (4), (b) (6)	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'mmHg'	System	24 Sep 2020 18:03:38

US3462364

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:41:23

US3462364

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 17:41:23

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:42:24

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 17:42:24

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 17:42:24

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 17:42:24

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:42:24

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '10:27'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:42:24

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '24 Sep 2020 10:27'	System	24 Sep 2020 17:42:24

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:42:24

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'ONCE'	System	24 Sep 2020 17:42:24

US3462364

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 17:42:24

US3462364

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:42:41

US3462364

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 17:42:41

US3462364

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '10:20'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:42:41

US3462364

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '24 Sep 2020 10:20'	System	24 Sep 2020 17:42:41

US3462364

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 17:43:00

US3462364

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		24 Sep 2020 17:43:00

US3462364

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:43:00

US3462364

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '10:20'	(b) (4), (b) (6)	24 Sep 2020 17:43:00

US3462364

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '24 Sep 2020 10:20'	System	24 Sep 2020 17:43:00

US3462364

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		24 Sep 2020 17:43:00

US3462364

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:53:42
User entered 'Yes (Y)'		24 Sep 2020 17:43:00

US3462364

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:53:42
User entered '10:20'		24 Sep 2020 17:43:00

US3462364

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered empty.	System	13 Oct 2020 00:53:42
User entered '24 Sep 2020 10:20'	System	24 Sep 2020 17:43:00

US3462364

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:24:40

US3462364

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'I'	System	01 Oct 2020 17:24:40

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:57:19', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f10c8d2c-9c78-4a66-96fa-fdff2f5fe863'	System	24 Sep 2020 17:57:39
User entered 'Yes (Y)'	System	24 Sep 2020 17:57:39

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:57:26', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f10c8d2c-9c78-4a66-96fa-fdff2f5fe863' User entered '98.4'	System	24 Sep 2020 17:57:39
	System	24 Sep 2020 17:57:39

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:57:30', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f10c8d2c-9c78-4a66-96fa-fdff2f5fe863'	System	24 Sep 2020 17:57:39
User entered 'No (N)'	System	24 Sep 2020 17:57:39

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:57:37', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f10c8d2c-9c78-4a66-96fa-fdff2f5fe863'	System	24 Sep 2020 17:57:39
User entered '24 Sep 2020 10:57'	System	24 Sep 2020 17:57:39

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '24 Sep 2020 10:47'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '24 Sep 2020 13:17'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:35:43', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '76c5fd5d-13d4-4563-be33-d9e3f61d1b47'	System	25 Sep 2020 02:36:07
User entered 'Yes (Y)'	System	25 Sep 2020 02:36:07

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:35:49', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '76c5fd5d-13d4-4563-be33-d9e3f61d1b47' User entered '97.1'	System	25 Sep 2020 02:36:07
	System	25 Sep 2020 02:36:07

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:35:56', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '76c5fd5d-13d4-4563-be33-d9e3f61d1b47'	System	25 Sep 2020 02:36:07
User entered 'No (N)'	System	25 Sep 2020 02:36:07

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:01', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '76c5fd5d-13d4-4563-be33-d9e3f61d1b47'	System	25 Sep 2020 02:36:07
User entered '24 Sep 2020 19:36'	System	25 Sep 2020 02:36:07

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '24 Sep 2020 14:12'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 2'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:26:42', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'aafcdcbe-bc7e-4085-a3cd-e518c111cf9f' User entered 'Yes (Y)'	System	26 Sep 2020 02:27:07
	System	26 Sep 2020 02:27:07

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:26:48', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'aafcdcbe-bc7e-4085-a3cd-e518c111cf9f' User entered '96.7'	System	26 Sep 2020 02:27:07
	System	26 Sep 2020 02:27:07

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:26:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'aafcdcbe-bc7e-4085-a3cd-e518c111cf9f' User entered 'No (N)'	System	26 Sep 2020 02:27:07
	System	26 Sep 2020 02:27:07

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:01', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'aafcdcbe-bc7e-4085-a3cd-e518c111cf9f' User entered '25 Sep 2020 19:27'	System	26 Sep 2020 02:27:07
	System	26 Sep 2020 02:27:07

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 3'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:02:10', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '5f641b0d-6bf7-4a42-b934-bd24fc3a3896'	System	27 Sep 2020 16:03:11
User entered 'Yes (Y)'	System	27 Sep 2020 16:03:11

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:02:47', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '5f641b0d-6bf7-4a42-b934-bd24fc3a3896'	System	27 Sep 2020 16:03:11
User entered '97.4'	System	27 Sep 2020 16:03:11

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:02:50', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '5f641b0d-6bf7-4a42-b934-bd24fc3a3896'	System	27 Sep 2020 16:03:11
User entered 'No (N)'	System	27 Sep 2020 16:03:11

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:02:55', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '5f641b0d-6bf7-4a42-b934-bd24fc3a3896'	System	27 Sep 2020 16:03:11
User entered '27 Sep 2020 09:02'	System	27 Sep 2020 16:03:11

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 4'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:21', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '935428d9-190d-408c-9562-bd09cbce6801'	System	28 Sep 2020 01:59:39
User entered 'Yes (Y)'	System	28 Sep 2020 01:59:39

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:27', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '935428d9-190d-408c-9562-bd09cbce6801' User entered '98.0'	System	28 Sep 2020 01:59:39
	System	28 Sep 2020 01:59:39

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:30', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '935428d9-190d-408c-9562-bd09cbce6801' User entered 'No (N)'	System	28 Sep 2020 01:59:39
	System	28 Sep 2020 01:59:39

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:35', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '935428d9-190d-408c-9562-bd09cbce6801'	System	28 Sep 2020 01:59:39
User entered '27 Sep 2020 18:59'	System	28 Sep 2020 01:59:39

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 5'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:49:54', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '09a03aed-9872-4cc5-8e56-f72ed02a67d0' User entered 'Yes (Y)'	System	29 Sep 2020 01:50:12
	System	29 Sep 2020 01:50:12

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:49:58', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '09a03aed-9872-4cc5-8e56-f72ed02a67d0' User entered '98.0'	System	29 Sep 2020 01:50:12
	System	29 Sep 2020 01:50:12

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:01', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '09a03aed-9872-4cc5-8e56-f72ed02a67d0'	System	29 Sep 2020 01:50:12
User entered 'No (N)'	System	29 Sep 2020 01:50:12

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:06', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '09a03aed-9872-4cc5-8e56-f72ed02a67d0'	System	29 Sep 2020 01:50:12
User entered '28 Sep 2020 18:50'	System	29 Sep 2020 01:50:12

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 6'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:03:42', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '13cecfed-3805-4a54-b6b5-cb8db38b3438' User entered 'Yes (Y)'	System	30 Sep 2020 01:03:58
	System	30 Sep 2020 01:03:58

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:03:48', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '13cecfed-3805-4a54-b6b5-cb8db38b3438' User entered '97.9'	System	30 Sep 2020 01:03:58
	System	30 Sep 2020 01:03:58

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:03:51', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '13cecfed-3805-4a54-b6b5-cb8db38b3438'	System	30 Sep 2020 01:03:58
User entered 'No (N)'	System	30 Sep 2020 01:03:58

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:03:55', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '13cecfed-3805-4a54-b6b5-cb8db38b3438'	System	30 Sep 2020 01:03:58
User entered '29 Sep 2020 18:03'	System	30 Sep 2020 01:03:58

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 7'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:47:24', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '72bfb9a5-599e-4911-a92b-b9660c69dc82'	System	01 Oct 2020 01:47:48
User entered 'Yes (Y)'	System	01 Oct 2020 01:47:48

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:47:29', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '72bfb9a5-599e-4911-a92b-b9660c69dc82' User entered '98.1'	System	01 Oct 2020 01:47:48
	System	01 Oct 2020 01:47:48

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:47:41', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '72bfb9a5-599e-4911-a92b-b9660c69dc82'	System	01 Oct 2020 01:47:48
User entered 'No (N)'	System	01 Oct 2020 01:47:48

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:47:45', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '72bfb9a5-599e-4911-a92b-b9660c69dc82'	System	01 Oct 2020 01:47:48
User entered '30 Sep 2020 18:47'	System	01 Oct 2020 01:47:48

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:57:43', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '6e6b7582-987f-49dd-94b0-ec615e22e755'	System	24 Sep 2020 17:57:58
User entered 'None (1)'	System	24 Sep 2020 17:57:58

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:57:46', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '6e6b7582-987f-49dd-94b0-ec615e22e755'	System	24 Sep 2020 17:57:58
User entered 'No (N)'	System	24 Sep 2020 17:57:58

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:57:48', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '6e6b7582-987f-49dd-94b0-ec615e22e755'	System	24 Sep 2020 17:57:58
User entered 'No (N)'	System	24 Sep 2020 17:57:58

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:57:51', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '6e6b7582-987f-49dd-94b0-ec615e22e755'	System	24 Sep 2020 17:57:58
User entered 'None (1)'	System	24 Sep 2020 17:57:58

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:57:55', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '6e6b7582-987f-49dd-94b0-ec615e22e755'	System	24 Sep 2020 17:57:58
User entered '24 Sep 2020 10:57'	System	24 Sep 2020 17:57:58

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '24 Sep 2020 10:47'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '24 Sep 2020 13:17'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:09', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f5c8b7d2-85b1-4b92-8f89-cade25ca2111' User entered 'None (1)'	System	25 Sep 2020 02:36:26
	System	25 Sep 2020 02:36:26

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:12', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f5c8b7d2-85b1-4b92-8f89-cade25ca2111' User entered 'No (N)'	System	25 Sep 2020 02:36:26
	System	25 Sep 2020 02:36:26

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:15', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f5c8b7d2-85b1-4b92-8f89-cade25ca2111' User entered 'No (N)'	System	25 Sep 2020 02:36:26
	System	25 Sep 2020 02:36:26

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:19', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f5c8b7d2-85b1-4b92-8f89-cade25ca2111' User entered 'None (1)'	System	25 Sep 2020 02:36:26
	System	25 Sep 2020 02:36:26

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:23', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f5c8b7d2-85b1-4b92-8f89-cade25ca2111' User entered '24 Sep 2020 19:36'	System	25 Sep 2020 02:36:26
	System	25 Sep 2020 02:36:26

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '24 Sep 2020 14:12'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 2'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:14', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4ddc3a1c-ef5a-45b7-b92d-7d8469079365'	System	26 Sep 2020 02:27:30
User entered 'None (1)'	System	26 Sep 2020 02:27:30

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:17', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4ddc3a1c-ef5a-45b7-b92d-7d8469079365'	System	26 Sep 2020 02:27:30
User entered 'No (N)'	System	26 Sep 2020 02:27:30

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:19', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4ddc3a1c-ef5a-45b7-b92d-7d8469079365'	System	26 Sep 2020 02:27:30
User entered 'No (N)'	System	26 Sep 2020 02:27:30

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:22', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4ddc3a1c-ef5a-45b7-b92d-7d8469079365' User entered 'None (1)'	System	26 Sep 2020 02:27:30
	System	26 Sep 2020 02:27:30

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:27', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '4ddc3a1c-ef5a-45b7-b92d-7d8469079365'	System	26 Sep 2020 02:27:30
User entered '25 Sep 2020 19:27'	System	26 Sep 2020 02:27:30

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 3'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'cf685d98-8363-4042-ad00-2808364a323a' User entered 'None (1)'	System	27 Sep 2020 16:03:25
	System	27 Sep 2020 16:03:25

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:03', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'cf685d98-8363-4042-ad00-2808364a323a' User entered 'No (N)'	System	27 Sep 2020 16:03:25
	System	27 Sep 2020 16:03:25

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:05', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'cf685d98-8363-4042-ad00-2808364a323a' User entered 'No (N)'	System	27 Sep 2020 16:03:25
	System	27 Sep 2020 16:03:25

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:09', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'cf685d98-8363-4042-ad00-2808364a323a' User entered 'None (1)'	System	27 Sep 2020 16:03:25
	System	27 Sep 2020 16:03:25

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:12', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'cf685d98-8363-4042-ad00-2808364a323a' User entered '27 Sep 2020 09:03'	System	27 Sep 2020 16:03:25
	System	27 Sep 2020 16:03:25

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 4'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:39', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd10c80dd-c8ce-447c-b255-38c58d9b4c17' User entered 'None (1)'	System	28 Sep 2020 01:59:53
	System	28 Sep 2020 01:59:53

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:42', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd10c80dd-c8ce-447c-b255-38c58d9b4c17'	System	28 Sep 2020 01:59:53
User entered 'No (N)'	System	28 Sep 2020 01:59:53

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:44', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd10c80dd-c8ce-447c-b255-38c58d9b4c17'	System	28 Sep 2020 01:59:53
User entered 'No (N)'	System	28 Sep 2020 01:59:53

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:47', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd10c80dd-c8ce-447c-b255-38c58d9b4c17' User entered 'None (1)'	System	28 Sep 2020 01:59:53
	System	28 Sep 2020 01:59:53

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:51', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd10c80dd-c8ce-447c-b255-38c58d9b4c17'	System	28 Sep 2020 01:59:53
User entered '27 Sep 2020 18:59'	System	28 Sep 2020 01:59:53

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 5'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:11', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '3822d835-665f-4771-a443-1862f5c723db' User entered 'None (1)'	System	29 Sep 2020 01:50:26
	System	29 Sep 2020 01:50:26

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:14', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '3822d835-665f-4771-a443-1862f5c723db' User entered 'No (N)'	System	29 Sep 2020 01:50:26
	System	29 Sep 2020 01:50:26

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:16', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '3822d835-665f-4771-a443-1862f5c723db' User entered 'No (N)'	System	29 Sep 2020 01:50:26
	System	29 Sep 2020 01:50:26

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:18', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '3822d835-665f-4771-a443-1862f5c723db' User entered 'None (1)'	System	29 Sep 2020 01:50:26
	System	29 Sep 2020 01:50:26

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:24', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '3822d835-665f-4771-a443-1862f5c723db' User entered '28 Sep 2020 18:50'	System	29 Sep 2020 01:50:26
	System	29 Sep 2020 01:50:26

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 6'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:01', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '628e5bf1-ea0e-41ea-8b5f-a4e2159ea85d' User entered 'None (1)'	System	30 Sep 2020 01:04:22
	System	30 Sep 2020 01:04:22

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:04', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '628e5bf1-ea0e-41ea-8b5f-a4e2159ea85d'	System	30 Sep 2020 01:04:22
User entered 'No (N)'	System	30 Sep 2020 01:04:22

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:06', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '628e5bf1-ea0e-41ea-8b5f-a4e2159ea85d'	System	30 Sep 2020 01:04:22
User entered 'No (N)'	System	30 Sep 2020 01:04:22

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:08', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '628e5bf1-ea0e-41ea-8b5f-a4e2159ea85d' User entered 'None (1)'	System	30 Sep 2020 01:04:22
	System	30 Sep 2020 01:04:22

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:20', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '628e5bf1-ea0e-41ea-8b5f-a4e2159ea85d' User entered '29 Sep 2020 18:04'	System	30 Sep 2020 01:04:22
	System	30 Sep 2020 01:04:22

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 7'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:47:50', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f2493a30-e271-4fcb-8333-9a8d9b66ae38'	System	01 Oct 2020 01:48:09
User entered 'None (1)'	System	01 Oct 2020 01:48:09

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:47:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f2493a30-e271-4fcb-8333-9a8d9b66ae38'	System	01 Oct 2020 01:48:09
User entered 'No (N)'	System	01 Oct 2020 01:48:09

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:47:55', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f2493a30-e271-4fcb-8333-9a8d9b66ae38'	System	01 Oct 2020 01:48:09
User entered 'No (N)'	System	01 Oct 2020 01:48:09

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:47:57', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f2493a30-e271-4fcb-8333-9a8d9b66ae38' User entered 'None (1)'	System	01 Oct 2020 01:48:09
	System	01 Oct 2020 01:48:09

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:48:03', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f2493a30-e271-4fcb-8333-9a8d9b66ae38'	System	01 Oct 2020 01:48:09
User entered '30 Sep 2020 18:48'	System	01 Oct 2020 01:48:09

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:58:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '03bfc5aa-63e8-4dad-96cf-57fe089b35e7' User entered 'None (0)'	System	24 Sep 2020 17:58:46
	System	24 Sep 2020 17:58:46

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:58:02', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '03bfc5aa-63e8-4dad-96cf-57fe089b35e7' User entered 'None (0)'	System	24 Sep 2020 17:58:46
	System	24 Sep 2020 17:58:46

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:58:05', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '03bfc5aa-63e8-4dad-96cf-57fe089b35e7' User entered 'None (0)'	System	24 Sep 2020 17:58:46
	System	24 Sep 2020 17:58:46

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:58:07', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '03bfc5aa-63e8-4dad-96cf-57fe089b35e7' User entered 'None (0)'	System	24 Sep 2020 17:58:46
	System	24 Sep 2020 17:58:46

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:58:10', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '03bfc5aa-63e8-4dad-96cf-57fe089b35e7' User entered 'None (0)'	System	24 Sep 2020 17:58:46
	System	24 Sep 2020 17:58:46

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:58:12', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '03bfc5aa-63e8-4dad-96cf-57fe089b35e7' User entered 'None (0)'	System	24 Sep 2020 17:58:46
	System	24 Sep 2020 17:58:46

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:58:15', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '03bfc5aa-63e8-4dad-96cf-57fe089b35e7' User entered 'No (N)'	System	24 Sep 2020 17:58:46
	System	24 Sep 2020 17:58:46

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T10:58:19', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '03bfc5aa-63e8-4dad-96cf-57fe089b35e7' User entered '24 Sep 2020 10:58'	System	24 Sep 2020 17:58:46
	System	24 Sep 2020 17:58:46

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '24 Sep 2020 10:47'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '24 Sep 2020 13:17'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:34', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '67feae1e-180a-4991-b992-9ae85e4cc138' User entered 'None (0)'	System	25 Sep 2020 02:37:06
	System	25 Sep 2020 02:37:06

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:43', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '67feae1e-180a-4991-b992-9ae85e4cc138' User entered 'None (0)'	System	25 Sep 2020 02:37:06
	System	25 Sep 2020 02:37:06

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:47', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '67feae1e-180a-4991-b992-9ae85e4cc138' User entered 'None (0)'	System	25 Sep 2020 02:37:06
	System	25 Sep 2020 02:37:06

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:50', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '67feae1e-180a-4991-b992-9ae85e4cc138' User entered 'None (0)'	System	25 Sep 2020 02:37:06
	System	25 Sep 2020 02:37:06

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '67feae1e-180a-4991-b992-9ae85e4cc138' User entered 'None (0)'	System	25 Sep 2020 02:37:06
	System	25 Sep 2020 02:37:06

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:55', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '67feae1e-180a-4991-b992-9ae85e4cc138' User entered 'None (0)'	System	25 Sep 2020 02:37:06
	System	25 Sep 2020 02:37:06

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:36:58', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '67feae1e-180a-4991-b992-9ae85e4cc138'	System	25 Sep 2020 02:37:06
User entered 'No (N)'	System	25 Sep 2020 02:37:06

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-24T19:37:03', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '67feae1e-180a-4991-b992-9ae85e4cc138' User entered '24 Sep 2020 19:37'	System	25 Sep 2020 02:37:06
	System	25 Sep 2020 02:37:06

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '24 Sep 2020 14:12'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 2'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:37', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0da7de7f-ad05-4b23-aa7e-bc54a666e75c' User entered 'None (0)'	System	26 Sep 2020 02:28:02
	System	26 Sep 2020 02:28:02

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:40', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0da7de7f-ad05-4b23-aa7e-bc54a666e75c' User entered 'None (0)'	System	26 Sep 2020 02:28:02
	System	26 Sep 2020 02:28:02

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:44', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0da7de7f-ad05-4b23-aa7e-bc54a666e75c' User entered 'None (0)'	System	26 Sep 2020 02:28:02
	System	26 Sep 2020 02:28:02

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:47', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0da7de7f-ad05-4b23-aa7e-bc54a666e75c' User entered 'None (0)'	System	26 Sep 2020 02:28:02
	System	26 Sep 2020 02:28:02

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:49', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0da7de7f-ad05-4b23-aa7e-bc54a666e75c' User entered 'None (0)'	System	26 Sep 2020 02:28:02
	System	26 Sep 2020 02:28:02

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:51', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0da7de7f-ad05-4b23-aa7e-bc54a666e75c' User entered 'None (0)'	System	26 Sep 2020 02:28:02
	System	26 Sep 2020 02:28:02

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:27:55', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0da7de7f-ad05-4b23-aa7e-bc54a666e75c' User entered 'No (N)'	System	26 Sep 2020 02:28:02
	System	26 Sep 2020 02:28:02

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-25T19:28:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0da7de7f-ad05-4b23-aa7e-bc54a666e75c' User entered '25 Sep 2020 19:28'	System	26 Sep 2020 02:28:02
	System	26 Sep 2020 02:28:02

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 3'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:16', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '69d67215-1614-4e77-8a8b-1519d9200eff' User entered 'None (0)'	System	27 Sep 2020 16:03:41
	System	27 Sep 2020 16:03:41

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:18', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '69d67215-1614-4e77-8a8b-1519d9200eff' User entered 'None (0)'	System	27 Sep 2020 16:03:41
	System	27 Sep 2020 16:03:41

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:21', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '69d67215-1614-4e77-8a8b-1519d9200eff' User entered 'None (0)'	System	27 Sep 2020 16:03:41
	System	27 Sep 2020 16:03:41

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:23', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '69d67215-1614-4e77-8a8b-1519d9200eff' User entered 'None (0)'	System	27 Sep 2020 16:03:41
	System	27 Sep 2020 16:03:41

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:26', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '69d67215-1614-4e77-8a8b-1519d9200eff' User entered 'None (0)'	System	27 Sep 2020 16:03:41
	System	27 Sep 2020 16:03:41

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:29', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '69d67215-1614-4e77-8a8b-1519d9200eff' User entered 'None (0)'	System	27 Sep 2020 16:03:41
	System	27 Sep 2020 16:03:41

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:33', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '69d67215-1614-4e77-8a8b-1519d9200eff' User entered 'No (N)'	System	27 Sep 2020 16:03:41
	System	27 Sep 2020 16:03:41

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T09:03:36', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '69d67215-1614-4e77-8a8b-1519d9200eff' User entered '27 Sep 2020 09:03'	System	27 Sep 2020 16:03:41
	System	27 Sep 2020 16:03:41

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 4'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:56', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1b6a20f2-cc0f-4606-a640-13678d6501a6'	System	28 Sep 2020 02:00:31
User entered 'None (0)'	System	28 Sep 2020 02:00:31

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:57', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1b6a20f2-cc0f-4606-a640-13678d6501a6'	System	28 Sep 2020 02:00:31
User entered 'None (0)'	System	28 Sep 2020 02:00:31

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T18:59:59', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1b6a20f2-cc0f-4606-a640-13678d6501a6'	System	28 Sep 2020 02:00:31
User entered 'None (0)'	System	28 Sep 2020 02:00:31

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T19:00:01', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1b6a20f2-cc0f-4606-a640-13678d6501a6' User entered 'None (0)'	System	28 Sep 2020 02:00:31
	System	28 Sep 2020 02:00:31

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T19:00:03', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1b6a20f2-cc0f-4606-a640-13678d6501a6'	System	28 Sep 2020 02:00:31
User entered 'None (0)'	System	28 Sep 2020 02:00:31

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T19:00:05', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1b6a20f2-cc0f-4606-a640-13678d6501a6'	System	28 Sep 2020 02:00:31
User entered 'None (0)'	System	28 Sep 2020 02:00:31

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T19:00:08', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1b6a20f2-cc0f-4606-a640-13678d6501a6'	System	28 Sep 2020 02:00:31
User entered 'No (N)'	System	28 Sep 2020 02:00:31

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-27T19:00:13', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1b6a20f2-cc0f-4606-a640-13678d6501a6'	System	28 Sep 2020 02:00:31
User entered '27 Sep 2020 19:00'	System	28 Sep 2020 02:00:31

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 5'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:30', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '19b04910-47e5-4071-8680-e22f236385f4'	System	29 Sep 2020 01:50:59
User entered 'None (0)'	System	29 Sep 2020 01:50:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:35', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '19b04910-47e5-4071-8680-e22f236385f4'	System	29 Sep 2020 01:50:59
User entered 'None (0)'	System	29 Sep 2020 01:50:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:39', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '19b04910-47e5-4071-8680-e22f236385f4'	System	29 Sep 2020 01:50:59
User entered 'None (0)'	System	29 Sep 2020 01:50:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:41', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '19b04910-47e5-4071-8680-e22f236385f4'	System	29 Sep 2020 01:50:59
User entered 'None (0)'	System	29 Sep 2020 01:50:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:43', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '19b04910-47e5-4071-8680-e22f236385f4'	System	29 Sep 2020 01:50:59
User entered 'None (0)'	System	29 Sep 2020 01:50:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:46', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '19b04910-47e5-4071-8680-e22f236385f4'	System	29 Sep 2020 01:50:59
User entered 'None (0)'	System	29 Sep 2020 01:50:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:49', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '19b04910-47e5-4071-8680-e22f236385f4'	System	29 Sep 2020 01:50:59
User entered 'No (N)'	System	29 Sep 2020 01:50:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-28T18:50:56', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '19b04910-47e5-4071-8680-e22f236385f4'	System	29 Sep 2020 01:50:59
User entered '28 Sep 2020 18:50'	System	29 Sep 2020 01:50:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 6'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:27', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f02f6c32-0380-4071-af7a-d5ad45a4242f'	System	30 Sep 2020 01:04:59
User entered 'No interference with activity (1)'	System	30 Sep 2020 01:04:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:32', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f02f6c32-0380-4071-af7a-d5ad45a4242f' User entered 'None (0)'	System	30 Sep 2020 01:04:59
	System	30 Sep 2020 01:04:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:35', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f02f6c32-0380-4071-af7a-d5ad45a4242f' User entered 'None (0)'	System	30 Sep 2020 01:04:59
	System	30 Sep 2020 01:04:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:38', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f02f6c32-0380-4071-af7a-d5ad45a4242f' User entered 'None (0)'	System	30 Sep 2020 01:04:59
	System	30 Sep 2020 01:04:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:41', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f02f6c32-0380-4071-af7a-d5ad45a4242f' User entered 'None (0)'	System	30 Sep 2020 01:04:59
	System	30 Sep 2020 01:04:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:43', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f02f6c32-0380-4071-af7a-d5ad45a4242f' User entered 'None (0)'	System	30 Sep 2020 01:04:59
	System	30 Sep 2020 01:04:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:49', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f02f6c32-0380-4071-af7a-d5ad45a4242f' User entered 'No (N)'	System	30 Sep 2020 01:04:59
	System	30 Sep 2020 01:04:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-29T18:04:56', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f02f6c32-0380-4071-af7a-d5ad45a4242f' User entered '29 Sep 2020 18:04'	System	30 Sep 2020 01:04:59
	System	30 Sep 2020 01:04:59

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	24 Sep 2020 17:42:24
User entered 'Day 7'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:48:15', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0c45261b-ee1c-40bf-ab4d-c036d10cfcf7' User entered 'None (0)'	System	01 Oct 2020 01:48:36
	System	01 Oct 2020 01:48:36

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:48:17', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0c45261b-ee1c-40bf-ab4d-c036d10cfcf7' User entered 'None (0)'	System	01 Oct 2020 01:48:36
	System	01 Oct 2020 01:48:36

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:48:18', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0c45261b-ee1c-40bf-ab4d-c036d10cfcf7' User entered 'None (0)'	System	01 Oct 2020 01:48:36
	System	01 Oct 2020 01:48:36

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:48:20', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0c45261b-ee1c-40bf-ab4d-c036d10cfcf7' User entered 'None (0)'	System	01 Oct 2020 01:48:36
	System	01 Oct 2020 01:48:36

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:48:21', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0c45261b-ee1c-40bf-ab4d-c036d10cfcf7' User entered 'None (0)'	System	01 Oct 2020 01:48:36
	System	01 Oct 2020 01:48:36

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:48:23', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0c45261b-ee1c-40bf-ab4d-c036d10cfcf7' User entered 'None (0)'	System	01 Oct 2020 01:48:36
	System	01 Oct 2020 01:48:36

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:48:26', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0c45261b-ee1c-40bf-ab4d-c036d10cfcf7'	System	01 Oct 2020 01:48:36
User entered 'No (N)'	System	01 Oct 2020 01:48:36

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-09-30T18:48:31', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '0c45261b-ee1c-40bf-ab4d-c036d10cfcf7' User entered '30 Sep 2020 18:48'	System	01 Oct 2020 01:48:36
	System	01 Oct 2020 01:48:36

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:42:24

US3462364

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:42:24

US3462364

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:24:50

US3462364

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:24:50

US3462364

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:24:50

US3462364

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:24:50

US3462364

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:18:36

US3462364

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'I'	System	08 Oct 2020 15:18:36

US3462364

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:19:07

US3462364

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:19:07

US3462364

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:19:07

US3462364

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:19:07

US3462364

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:41:32

US3462364

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'I'	System	21 Oct 2020 16:41:32

US3462364

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:42:27

US3462364

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:42:27

US3462364

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:42:27

US3462364

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 16:42:27

US3462364

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:27:11

US3462364

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'I'	System	22 Oct 2020 20:27:11

US3462364

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:27:37

US3462364

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:27:37

US3462364

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:27:37

US3462364

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'VISIT3'	System	22 Oct 2020 20:27:37

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered empty.	System	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered empty.	System	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered empty.	System	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered empty.	System	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered empty.	System	22 Oct 2020 20:27:46

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42

US3462364

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42

US3462364

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:27:56

US3462364

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 20:27:56

US3462364

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:28:13

US3462364

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:28:13

US3462364

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered '13:15'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:28:13

US3462364

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered '22 Oct 2020 13:15'	System	22 Oct 2020 20:28:13

US3462364

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:59:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:14:27

US3462364

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'I'	System	05 Nov 2020 22:14:27

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 64'	System	27 Aug 2020 19:52:30

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-10-29T12:00:59', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '45825080-df88-4fb7-8540-c6baaff5b332'	System	29 Oct 2020 19:01:19
User entered 'No (N)'	System	29 Oct 2020 19:01:19

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Have you been exposed to someone with 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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-10-29T12:01:05', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '45825080-df88-4fb7-8540-c6baaff5b332'	System	29 Oct 2020 19:01:19
User entered 'No (N)'	System	29 Oct 2020 19:01:19

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-10-29T12:01:15', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '45825080-df88-4fb7-8540-c6baaff5b332'	System	29 Oct 2020 19:01:19
User entered '29 Oct 2020 12:01:15'	System	29 Oct 2020 19:01:19

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 19:52:30

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 71'	System	27 Aug 2020 19:52:30

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-11-05T13:02:41', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f0e2c1cd-0ea0-47be-b80d-9f4c337b49f6'	System	05 Nov 2020 21:02:52
User entered 'No (N)'	System	05 Nov 2020 21:02:52

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-11-05T13:02:46', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f0e2c1cd-0ea0-47be-b80d-9f4c337b49f6'	System	05 Nov 2020 21:02:52
User entered 'No (N)'	System	05 Nov 2020 21:02:52

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-11-05T13:02:49', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'f0e2c1cd-0ea0-47be-b80d-9f4c337b49f6' User entered '05 Nov 2020 13:02:49'	System	05 Nov 2020 21:02:52
	System	05 Nov 2020 21:02:52

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 19:52:30

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered 'Day 78'	System	27 Aug 2020 19:52:30

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-11-12T08:53:45', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '960fc1a6-8e50-4bff-8c55-49d929556853'	System	12 Nov 2020 16:53:58
User entered 'No (N)'	System	12 Nov 2020 16:53:58

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Have you been exposed to someone with 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 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-11-12T08:53:50', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '960fc1a6-8e50-4bff-8c55-49d929556853'	System	12 Nov 2020 16:53:58
User entered 'No (N)'	System	12 Nov 2020 16:53:58

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-11-12T08:53:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '960fc1a6-8e50-4bff-8c55-49d929556853'	System	12 Nov 2020 16:53:58
User entered '12 Nov 2020 08:53:53'	System	12 Nov 2020 16:53:58

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 19:52:30

US3462364

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:44:44
Data entry locked.	System	27 Aug 2020 19:52:30
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 19:52:30

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-01T17:59:30', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '90d05f28-39fe-4bbe-8eab-16cace75be36' User entered 'No (N)'	System	02 Dec 2020 01:59:46
	System	02 Dec 2020 01:59:46

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-01T17:59:35', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '90d05f28-39fe-4bbe-8eab-16cace75be36'	System	02 Dec 2020 01:59:46
User entered 'No (N)'	System	02 Dec 2020 01:59:46

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-01T17:59:40', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '90d05f28-39fe-4bbe-8eab-16cace75be36' User entered '01 Dec 2020 17:59:40'	System	02 Dec 2020 01:59:46
	System	02 Dec 2020 01:59:46

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-07T12:00:24', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '6ebec779-5e62-420f-96fa-1a46e66d9c6b'	System	07 Dec 2020 20:00:38
User entered 'No (N)'	System	07 Dec 2020 20:00:38

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-07T12:00:29', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '6ebec779-5e62-420f-96fa-1a46e66d9c6b'	System	07 Dec 2020 20:00:38
User entered 'No (N)'	System	07 Dec 2020 20:00:38

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-07T12:00:35', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '6ebec779-5e62-420f-96fa-1a46e66d9c6b' User entered '07 Dec 2020 12:00:35'	System	07 Dec 2020 20:00:38
	System	07 Dec 2020 20:00:38

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-12T06:53:38', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'c34a7f10-94fe-4236-814a-6fa94ec4d2f1' User entered 'No (N)'	System	12 Dec 2020 14:53:46
	System	12 Dec 2020 14:53:46

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-12T06:53:42', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'c34a7f10-94fe-4236-814a-6fa94ec4d2f1'	System	12 Dec 2020 14:53:46
User entered 'No (N)'	System	12 Dec 2020 14:53:46

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-12T06:53:45', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'c34a7f10-94fe-4236-814a-6fa94ec4d2f1' User entered '12 Dec 2020 06:53:45'	System	12 Dec 2020 14:53:46
	System	12 Dec 2020 14:53:46

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-19T08:34:33', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e088ec72-7658-4ee8-bdf9-c26ca6898106'	System	19 Dec 2020 16:34:42
User entered 'No (N)'	System	19 Dec 2020 16:34:42

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-19T08:34:37', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e088ec72-7658-4ee8-bdf9-c26ca6898106'	System	19 Dec 2020 16:34:42
User entered 'No (N)'	System	19 Dec 2020 16:34:42

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-19T08:34:40', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e088ec72-7658-4ee8-bdf9-c26ca6898106' User entered '19 Dec 2020 08:34:40'	System	19 Dec 2020 16:34:42
	System	19 Dec 2020 16:34:42

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-26T08:23:42', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'dda5f8bc-f9bf-4431-a8b3-fdb0051a3b83'	System	26 Dec 2020 16:23:55
User entered 'No (N)'	System	26 Dec 2020 16:23:55

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-26T08:23:45', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'dda5f8bc-f9bf-4431-a8b3-fdb0051a3b83'	System	26 Dec 2020 16:23:55
User entered 'No (N)'	System	26 Dec 2020 16:23:55

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2020-12-26T08:23:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'dda5f8bc-f9bf-4431-a8b3-fdb0051a3b83' User entered '26 Dec 2020 08:23:53'	System	26 Dec 2020 16:23:55
	System	26 Dec 2020 16:23:55

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-05T19:42:45', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2537807b-eb56-4533-b2a2-ed8dd11c039a'	System	06 Jan 2021 03:42:57
User entered 'No (N)'	System	06 Jan 2021 03:42:57

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-05T19:42:50', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2537807b-eb56-4533-b2a2-ed8dd11c039a'	System	06 Jan 2021 03:42:57
User entered 'No (N)'	System	06 Jan 2021 03:42:57

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-05T19:42:53', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2537807b-eb56-4533-b2a2-ed8dd11c039a' User entered '05 Jan 2021 19:42:53'	System	06 Jan 2021 03:42:57
	System	06 Jan 2021 03:42:57

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-12T18:07:12', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '473b45a3-2696-4eaa-961e-aecac873501f' User entered 'No (N)'	System	13 Jan 2021 02:07:24
	System	13 Jan 2021 02:07:24

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-12T18:07:16', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '473b45a3-2696-4eaa-961e-aecac873501f' User entered 'No (N)'	System	13 Jan 2021 02:07:24

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-12T18:07:18', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '473b45a3-2696-4eaa-961e-aecac873501f' User entered '12 Jan 2021 18:07:18'	System	13 Jan 2021 02:07:24

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-16T03:57:10', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'dae42bf0-5a03-4c1b-a0fa-2b3ba1c5e027'	System	16 Jan 2021 11:57:24
User entered 'No (N)'	System	16 Jan 2021 11:57:24

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-16T03:57:15', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'dae42bf0-5a03-4c1b-a0fa-2b3ba1c5e027'	System	16 Jan 2021 11:57:24
User entered 'No (N)'	System	16 Jan 2021 11:57:24

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-16T03:57:21', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'dae42bf0-5a03-4c1b-a0fa-2b3ba1c5e027' User entered '16 Jan 2021 03:57:21'	System	16 Jan 2021 11:57:24
	System	16 Jan 2021 11:57:24

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-24T05:37:31', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '35e96afc-e9e8-4cb5-b42e-c5cb120f6b05' User entered 'No (N)'	System	24 Jan 2021 13:37:44
	System	24 Jan 2021 13:37:44

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-24T05:37:38', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '35e96afc-e9e8-4cb5-b42e-c5cb120f6b05'	System	24 Jan 2021 13:37:44
User entered 'No (N)'	System	24 Jan 2021 13:37:44

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-01-24T05:37:41', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '35e96afc-e9e8-4cb5-b42e-c5cb120f6b05' User entered '24 Jan 2021 05:37:41'	System	24 Jan 2021 13:37:44

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-02T17:59:26', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '48a4c272-f31c-4314-9799-d8a18f927ffc'	System	03 Feb 2021 01:59:38
User entered 'No (N)'	System	03 Feb 2021 01:59:38

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-02T17:59:29', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '48a4c272-f31c-4314-9799-d8a18f927ffc' User entered 'No (N)'	System	03 Feb 2021 01:59:38

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-02T17:59:32', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '48a4c272-f31c-4314-9799-d8a18f927ffc' User entered '02 Feb 2021 17:59:32'	System	03 Feb 2021 01:59:38
	System	03 Feb 2021 01:59:38

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-08T12:00:52', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '038b74df-fa17-4bd0-9072-6fd59a92bfe2'	System	08 Feb 2021 20:01:48
User entered 'No (N)'	System	08 Feb 2021 20:01:48

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-08T12:00:56', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '038b74df-fa17-4bd0-9072-6fd59a92bfe2'	System	08 Feb 2021 20:01:48
User entered 'No (N)'	System	08 Feb 2021 20:01:48

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-08T12:00:59', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '038b74df-fa17-4bd0-9072-6fd59a92bfe2' User entered '08 Feb 2021 12:00:59'	System	08 Feb 2021 20:01:48
	System	08 Feb 2021 20:01:48

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-13T08:05:08', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '56bf9b36-0e90-4278-8b63-1be68930b4d4'	System	13 Feb 2021 16:05:17
User entered 'No (N)'	System	13 Feb 2021 16:05:17

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-13T08:05:10', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '56bf9b36-0e90-4278-8b63-1be68930b4d4'	System	13 Feb 2021 16:05:17
User entered 'No (N)'	System	13 Feb 2021 16:05:17

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-13T08:05:14', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '56bf9b36-0e90-4278-8b63-1be68930b4d4'	System	13 Feb 2021 16:05:17
User entered '13 Feb 2021 08:05:14'	System	13 Feb 2021 16:05:17

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-22T12:00:32', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '20c0d04a-e10e-4e15-a09f-2c15064d970d' User entered 'No (N)'	System	22 Feb 2021 20:01:05
	System	22 Feb 2021 20:01:05

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-22T12:00:35', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '20c0d04a-e10e-4e15-a09f-2c15064d970d' User entered 'No (N)'	System	22 Feb 2021 20:01:05
	System	22 Feb 2021 20:01:05

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-22T12:00:39', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '20c0d04a-e10e-4e15-a09f-2c15064d970d' User entered '22 Feb 2021 12:00:39'	System	22 Feb 2021 20:01:05
	System	22 Feb 2021 20:01:05

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-27T07:24:20', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'a9f12525-dd03-48bf-bd29-41ede793a474' User entered 'No (N)'	System	27 Feb 2021 15:24:36
	System	27 Feb 2021 15:24:36

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-27T07:24:25', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'a9f12525-dd03-48bf-bd29-41ede793a474' User entered 'No (N)'	System	27 Feb 2021 15:24:36

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-27T07:24:29', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'a9f12525-dd03-48bf-bd29-41ede793a474' User entered '27 Feb 2021 07:24:29'	System	27 Feb 2021 15:24:36
	System	27 Feb 2021 15:24:36

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-08T12:04:52', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2c808f9a-abcf-4dbe-b280-c683bb55d565'	System	08 Mar 2021 20:05:17
User entered 'No (N)'	System	08 Mar 2021 20:05:17

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-08T12:04:54', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2c808f9a-abcf-4dbe-b280-c683bb55d565'	System	08 Mar 2021 20:05:17
User entered 'No (N)'	System	08 Mar 2021 20:05:17

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-08T12:04:58', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '2c808f9a-abcf-4dbe-b280-c683bb55d565' User entered '08 Mar 2021 12:04:58'	System	08 Mar 2021 20:05:17
	System	08 Mar 2021 20:05:17

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-15T19:22:27', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'cff28b7f-db69-466c-a51f-cfa07ac78c25'	System	16 Mar 2021 02:22:37
User entered 'No (N)'	System	16 Mar 2021 02:22:37

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-15T19:22:30', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'cff28b7f-db69-466c-a51f-cfa07ac78c25'	System	16 Mar 2021 02:22:37
User entered 'No (N)'	System	16 Mar 2021 02:22:37

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-15T19:22:33', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'cff28b7f-db69-466c-a51f-cfa07ac78c25' User entered '15 Mar 2021 19:22:33'	System	16 Mar 2021 02:22:37
	System	16 Mar 2021 02:22:37

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-24T11:59:21-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b8c58e4f-a7ac-4d11-bc07-6753ab19afe0'	System	24 Mar 2021 18:59:30
User entered 'No (N)'	System	24 Mar 2021 18:59:30

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-24T11:59:24-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b8c58e4f-a7ac-4d11-bc07-6753ab19afe0'	System	24 Mar 2021 18:59:30
User entered 'No (N)'	System	24 Mar 2021 18:59:30

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-24T11:59:27-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'b8c58e4f-a7ac-4d11-bc07-6753ab19afe0' User entered '24 Mar 2021 11:59:27'	System	24 Mar 2021 18:59:30
	System	24 Mar 2021 18:59:30

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-27T05:59:04-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'a7075818-4dd8-4be8-ad25-dfd4ac273aff'	System	27 Mar 2021 12:59:18
User entered 'No (N)'	System	27 Mar 2021 12:59:18

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-27T05:59:09-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'a7075818-4dd8-4be8-ad25-dfd4ac273aff'	System	27 Mar 2021 12:59:18
User entered 'No (N)'	System	27 Mar 2021 12:59:18

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-03-27T05:59:13-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'a7075818-4dd8-4be8-ad25-dfd4ac273aff'	System	27 Mar 2021 12:59:18
User entered '27 Mar 2021 05:59:13'	System	27 Mar 2021 12:59:18

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-03T06:14:47-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd508265f-68d3-4e7b-b038-d1114d7755fb' User entered 'No (N)'	System	03 Apr 2021 13:15:00
	System	03 Apr 2021 13:15:00

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-03T06:14:53-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd508265f-68d3-4e7b-b038-d1114d7755fb' User entered 'No (N)'	System	03 Apr 2021 13:15:00
	System	03 Apr 2021 13:15:00

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-03T06:14:58-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'd508265f-68d3-4e7b-b038-d1114d7755fb'	System	03 Apr 2021 13:15:00
User entered '03 Apr 2021 06:14:58'	System	03 Apr 2021 13:15:00

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-12T12:00:51-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'fbe12c67-289c-437e-a689-775aa1c4d54f' User entered 'No (N)'	System	12 Apr 2021 19:01:22
	System	12 Apr 2021 19:01:22

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-12T12:00:55-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'fbe12c67-289c-437e-a689-775aa1c4d54f'	System	12 Apr 2021 19:01:22
User entered 'No (N)'	System	12 Apr 2021 19:01:22

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-12T12:00:58-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'fbe12c67-289c-437e-a689-775aa1c4d54f'	System	12 Apr 2021 19:01:22
User entered '12 Apr 2021 12:00:58'	System	12 Apr 2021 19:01:22

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-19T12:00:39-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '074a2c59-d600-461f-ae5c-60c5709f16d3' User entered 'No (N)'	System	19 Apr 2021 19:01:09
	System	19 Apr 2021 19:01:09

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-19T12:00:42-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '074a2c59-d600-461f-ae5c-60c5709f16d3'	System	19 Apr 2021 19:01:09
User entered 'No (N)'	System	19 Apr 2021 19:01:09

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-19T12:00:46-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '074a2c59-d600-461f-ae5c-60c5709f16d3'	System	19 Apr 2021 19:01:09
User entered '19 Apr 2021 12:00:46'	System	19 Apr 2021 19:01:09

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-26T12:19:20-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1a54f31d-d079-4b53-ab15-2b5b2b369123'	System	26 Apr 2021 19:19:45
User entered 'No (N)'	System	26 Apr 2021 19:19:45

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-26T12:19:38-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1a54f31d-d079-4b53-ab15-2b5b2b369123'	System	26 Apr 2021 19:19:45
User entered 'No (N)'	System	26 Apr 2021 19:19:45

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-04-26T12:19:43-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '1a54f31d-d079-4b53-ab15-2b5b2b369123'	System	26 Apr 2021 19:19:45
User entered '26 Apr 2021 12:19:43'	System	26 Apr 2021 19:19:45

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-05-01T07:23:19-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '100f00d4-9a9a-4983-a1aa-c17adf27826c'	System	01 May 2021 14:23:26
User entered 'No (N)'	System	01 May 2021 14:23:26

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Have you been exposed to someone with 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 (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-05-01T07:23:21-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '100f00d4-9a9a-4983-a1aa-c17adf27826c'	System	01 May 2021 14:23:26
User entered 'No (N)'	System	01 May 2021 14:23:26

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-05-01T07:23:24-07:00', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: '100f00d4-9a9a-4983-a1aa-c17adf27826c'	System	01 May 2021 14:23:26
User entered '01 May 2021 07:23:24'	System	01 May 2021 14:23:26

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:19:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:19:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:19:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:19:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:19:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:19:13

US3462364

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:19:13
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:19:13

US3462364

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:11

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 07:26:47
User closed query 'Per CDM Review: "Have you eve received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 12:06:53
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'Spoke with pt. about facial cosmetic injections diary alert. Pt reported having therapy for migraines that were occurring over 5 years ago. Pt has had no reaction from the vaccine or any symptoms with those facial injections. No further information needed. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:49:02
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 22:11:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-27T07:24:45', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e7abb352-08da-4ea8-b914-bbe3a1e70ece'	System	27 Feb 2021 15:25:26
User entered 'Yes (Y)'	System	27 Feb 2021 15:25:26

US3462364

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:11

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:26:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-27T07:24:57', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e7abb352-08da-4ea8-b914-bbe3a1e70ece'	System	27 Feb 2021 15:25:26
User entered 'No (N)'	System	27 Feb 2021 15:25:26

US3462364

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:26:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C76EA8D3-AAEE-4F38-803B-738CEB8F9981)', Time: '2021-02-27T07:25:15', User OID: 'PatientReportedOutcome (US3462364)', ODM File OID: 'e7abb352-08da-4ea8-b914-bbe3a1e70ece' User entered '27 Feb 2021 07:25:15'	System	27 Feb 2021 15:25:26
	System	27 Feb 2021 15:25:26

US3462364

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:19:31

US3462364

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:19:31

US3462364

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:19:31

US3462364

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:19:31

US3462364

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:19:38

US3462364

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:51:42
User entered 'I'	System	19 Nov 2020 18:19:38

US3462364

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:07:15

US3462364

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:07:15

US3462364

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:07:15

US3462364

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:07:15

US3462364

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:07:20

US3462364

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User entered 'I'	System	04 Jan 2021 21:07:20

US3462364

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 20:10:18

US3462364

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '23 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 20:10:18

US3462364

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:10:18

US3462364

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 20:10:18

US3462364

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:10:27

US3462364

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:23:00
User entered 'I'	System	27 Jan 2021 20:10:27

US3462364

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:09:31
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 entered 'No (N)' reason for change: Data Entry Error	System	08 Apr 2021 18:50:48
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).	(b) (4), (b) (6)	08 Apr 2021 18:50:48
User entered 'Yes (Y)'	System	24 Mar 2021 17:51:43
	(b) (4), (b) (6)	24 Mar 2021 17:51:43

US3462364

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:43

US3462364

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:43

US3462364

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:43

US3462364

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:51:49

US3462364

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:30
User entered 'I'	System	24 Mar 2021 17:51:49

US3462364

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:52:21

US3462364

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:52:21

US3462364

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:52:21

US3462364

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'VISIT4'	System	24 Mar 2021 17:52:21

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:23:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:23:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:23:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:23:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:23:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:23:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:23:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:23:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:23:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:23:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered empty.	System	01 Apr 2021 19:19:12

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13

US3462364

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13

US3462364

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:52:29

US3462364

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:52:29

US3462364

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:52:45

US3462364

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:52:45

US3462364

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '14:05'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:52:45

US3462364

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered '23 Mar 2021 14:05'	System	24 Mar 2021 17:52:45

US3462364

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:52:53

US3462364

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:11:13
User entered 'I'	System	24 Mar 2021 17:52:53

US3462364

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:46:17

US3462364

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:46:17

US3462364

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:46:17

US3462364

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'UNBLND_DECIDE'	System	23 Jan 2021 20:46:17

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:46:36

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:53:59
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:10:06

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:46:36

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:09:31
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:23:55
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'A6 Updated ' (Sit from DM).		08 Apr 2021 20:54:55
User entered 'Amendment 6 or later (Amendment 6 or later)'		08 Apr 2021 20:53:59
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		08 Apr 2021 20:11:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:10:06

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:46:36

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:46:36

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	23 Jan 2021 20:46:36

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:46:36

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Jan 2021 20:46:36

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '1'	System	23 Jan 2021 20:46:36

US3462364

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'I'	System	23 Jan 2021 20:46:36

US3462364

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '167.6' cm	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '90.7' kg	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '32.28935'	System	23 Jan 2021 20:48:29
DataPoint set to visible.	System	23 Jan 2021 20:46:36

US3462364

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '167.6' cm	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '90.7' kg	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '32.28935'	System	23 Jan 2021 20:48:29
DataPoint set to visible.	System	23 Jan 2021 20:46:36

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User accepted default value 'Pre-Dose (PREDOSE)'		23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '15:01'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '18 Jan 2021 15:01'	System	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '97.4' F	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Tympanic'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '86'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'bpm'	System	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '18'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'breaths/min'	System	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '142'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'mmHg'	System	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '84'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'mmHg'	System	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '167.6' cm	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '90.7' kg	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '32.28935'	System	23 Jan 2021 20:48:29
DataPoint set to visible.	System	23 Jan 2021 20:46:36

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User accepted default value 'Post-Dose (POSTDOSE)'		23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '16:15'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '18 Jan 2021 16:15'	System	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '97.1' F	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Other (Other)'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Tympanic'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '79'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'bpm'	System	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '16'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'breaths/min'	System	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '124'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'mmHg'	System	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '84'	(b) (4), (b) (6)	23 Jan 2021 20:48:29

US3462364

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'mmHg'	System	23 Jan 2021 20:48:29

US3462364

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:49:02

US3462364

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:49:02

US3462364

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:49:37

US3462364

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered empty.	(b) (4), (b) (6)	23 Jan 2021 20:49:37

US3462364

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

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)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered empty.	(b) (4), (b) (6)	23 Jan 2021 20:49:37

US3462364

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'mRNA-1273'	System	23 Jan 2021 20:49:37
DataPoint set to visible.	System	23 Jan 2021 20:46:36

US3462364

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:49:37

US3462364

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '15:45'	(b) (4), (b) (6)	23 Jan 2021 20:49:37

US3462364

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '18 Jan 2021 15:45'	System	23 Jan 2021 20:49:37

US3462364

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:49:37

US3462364

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'ONCE'	System	23 Jan 2021 20:49:37

US3462364

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'INTRAMUSCULAR'	System	23 Jan 2021 20:49:37

US3462364

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Jan 2021 20:46:46

US3462364

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '18 Jan 2021'	(b) (4), (b) (6)	23 Jan 2021 20:46:46

US3462364

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '14:40'	(b) (4), (b) (6)	23 Jan 2021 20:46:46

US3462364

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '18 Jan 2021 14:40'	System	23 Jan 2021 20:46:46

US3462364

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:46:55

US3462364

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:46:55

US3462364

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered '14:24'	(b) (4), (b) (6)	23 Jan 2021 20:46:55

US3462364

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:11

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '18 Jan 2021 14:24'	System	23 Jan 2021 20:46:55

US3462364

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

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 20:49:43

US3462364

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

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'I'	System	23 Jan 2021 20:49:43

US3462364

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:54:43

US3462364

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:54:43

US3462364

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:54:43

US3462364

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:56
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:54:43

US3462364

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:53:47

US3462364

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'I'	System	24 Mar 2021 17:53:47

US3462364

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '1'	System	24 Mar 2021 17:53:47
DataPoint set to visible.	System	24 Mar 2021 17:53:47

US3462364

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:19

US3462364

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).		26 Mar 2021 07:26:23
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:57:12
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'unknown why it was done out of range, per source document date it correct' (Site from System).		24 Mar 2021 17:55:26
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Mar 2021 17:55:19
User entered '25 Jan 2021'	(b) (4), (b) (6)	24 Mar 2021 17:55:19

US3462364

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:19

US3462364

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'OLD29'	System	24 Mar 2021 17:55:19

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User accepted default value 'Pre-Dose (PREDOSE)'		24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	24 Mar 2021 17:57:12
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Mar 2021 17:56:46
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '13:08'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '24 Feb 2021 13:08'	System	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '82'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'bpm'	System	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '13'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'breaths/min'	System	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '129'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'mmHg'	System	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '84'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'mmHg'	System	24 Mar 2021 17:56:46

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User accepted default value 'Post-Dose (POSTDOSE)'		24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '13:54'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '24 Feb 2021 13:54'	System	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '84'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'bpm'	System	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '14'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'breaths/min'	System	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '116'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'mmHg'	System	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '81'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'mmHg'	System	24 Mar 2021 17:58:01

US3462364

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:17

US3462364

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:17

US3462364

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3462364

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3462364

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

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)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3462364

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'mRNA-1273'	System	24 Mar 2021 17:58:45
DataPoint set to visible.	System	24 Mar 2021 17:53:47

US3462364

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3462364

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '13:24'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3462364

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '24 Feb 2021 13:24'	System	24 Mar 2021 17:58:45

US3462364

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:45

US3462364

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'ONCE'	System	24 Mar 2021 17:58:45

US3462364

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'INTRAMUSCULAR'	System	24 Mar 2021 17:58:45

US3462364

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:52

US3462364

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'I'	System	24 Mar 2021 17:58:52

US3462364

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:00:10

US3462364

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	24 Mar 2021 18:01:08
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 18:01:08
User entered '27 Feb 2021' reason for change: Data Entry Error		24 Mar 2021 18:00:37
User entered '08 Mar 2021' reason for change: Data Entry Error		24 Mar 2021 18:00:24
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Mar 2021 18:00:10
User entered '28 Feb 2021'	(b) (4), (b) (6)	24 Mar 2021 18:00:10

US3462364

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:00:10

US3462364

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:00:10

US3462364

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:13

US3462364

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'I'	System	24 Mar 2021 18:01:13

US3462364

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:26

US3462364

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:26

US3462364

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:26

US3462364

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered 'OLD57'	System	24 Mar 2021 18:01:26

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered empty.	System	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered empty.	System	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered empty.	System	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered empty.	System	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered empty.	System	24 Mar 2021 18:01:33

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28

US3462364

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28

US3462364

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:45

US3462364

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:01:45

US3462364

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:02:10

US3462364

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:02:10

US3462364

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:22:32
User entered '14:05'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:02:10

US3462364

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:33:28
User entered '23 Mar 2021 14:05'	System	24 Mar 2021 18:02:10

US3462364

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:40:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:19:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:59:00

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered	(b) (4)	
'USA-US093-2021-mRNA-1273-P301000007'	System	25 Feb 2021 19:15:22
User entered 'New'	(b) (4), (b) (6)	25 Feb 2021 19:15:22

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Feb 2021 23:03:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 23:03:06
Data point term sent to Coder	System	24 Feb 2021 23:02:14
User entered 'Kidney Stones'	(b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
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).	(b) (4)	24 Feb 2021 23:04:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 23:04:45
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	24 Feb 2021 23:02:07
User entered '10:00'	(b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 23:04:45
User entered '6 Feb 2021 10:00'	System	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
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).	(b) (4)	24 Feb 2021 23:04:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 23:04:45
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	24 Feb 2021 23:02:07
User entered '16:00'	(b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 23:04:45
User entered '8 Feb 2021 16:00'	System	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	24 Feb 2021 23:04:45
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Feb 2021 23:02:07
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	24 Feb 2021 23:04:45
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	24 Feb 2021 23:04:45
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 23:04:45
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	24 Feb 2021 23:02:07
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Medical records are unable to be obtained and records have been requested multiple times but have not received them yet. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 May 2021 16:24:44
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redact and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).		02 Mar 2021 19:29:11
User entered '9 Feb 2021'		24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	24 Feb 2021 23:04:45
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Feb 2021 23:02:07
User entered '0'	(b) (4), (b) (6) (b) (4)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:04:45
User entered '0'		24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
Query 'Per DM CLR: SAE Narrative = ON 08FEB2021 PT HAD A LITHOTRIPSY PROCEDURE DONE TO REMOVE THE KIDNEY STONES. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'updated ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 May 2021 16:37:17
Query 'PV Query: Once records are available, please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. Please leave query unanswered until information is available. If unable to obtain or test not done, please state so.' answered with 'At Providence Medford Medical Center on 07FEB2021 patient tested negative for a Covid-19 rapid antigen test. ' (Site from Safety).		03 May 2021 16:34:23
User opened query 'Per DM CLR: SAE Narrative = ON 08FEB2021 PT HAD A LITHOTRIPSY PROCEDURE DONE TO REMOVE THE KIDNEY STONES. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		14 Mar 2021 18:30:03
User opened query 'PV Query: Once records are available, please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. Please leave query unanswered until information is available. If unable to obtain or test not done, please state so.' (Site from Safety).		05 Mar 2021 21:06:23
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).		05 Mar 2021 20:19:24

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Per no medical records unknow if labs were done and what the results were ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 17:59:19
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).		02 Mar 2021 19:29:20
User entered 'On 06Feb2021 Pt reported having extreme back pain that persisted all day. Around 1900 on 06feb2021 pt went into Urgent Care in Grants Pass, Oregon to have her extreme back pain looked at. At Urgent Care pt was diagnosed with having kidney stones which is not unusual as the pt has a medical history of having kidney stones. The following day 07Feb2021 the pt was still in extreme back pain and returned to Urgent Care at 1900. Pt was then transported via ambulance to Providence Medford Medical Center at around 2100. Pt stayed in hospital from 07Feb2021 to 09Feb2021. On 08Feb2021 pt had a Lithotripsy procedure done to remove the kidney stones. Pt was prescribed 5mg Oxycodone which the pt took once daily from 09Feb2021 to 10Feb2021. Pt reports no current symptoms and extreme back pain has resolved.'		24 Feb 2021 23:40:48
reason for change: Data Entry Error		
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Feb 2021 23:04:45
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	24 Feb 2021 23:04:45
User entered 'Refer to progress note in patients chart'	(b) (4), (b) (6)	24 Feb 2021 23:04:45
reason for change: Data Entry Error		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Feb 2021 23:02:07
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 23:02:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

1828 of 1935

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 23:02:07

US3462364

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 23:02:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:19:48
User closed query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile.' (Site from DM).		01 May 2021 14:13:39
Query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile.' answered with 'Updated and added to conmed log ' (Site from DM).		29 Apr 2021 17:21:16
User opened query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile.' (Site from DM).		16 Apr 2021 20:35:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:40:09
User entered 'No (N)'		01 Sep 2020 01:00:17

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 21:05:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:05:28
Data point term sent to Coder	System	04 Nov 2020 16:42:03
User entered 'Ibuprofen (3tabs)'	(b) (4), (b) (6) (b) (4)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'Injection side pain in Right Deltoid'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered '220'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:41:37

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
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)	19 Nov 2020 18:31:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 18:31:01
Data point term sent to Coder	System	19 Nov 2020 18:29:57
User entered 'Influenza Vaccine'	(b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'Influenza Prophylaxis'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered '0.5'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:38:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User entered empty.	System	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User entered empty.	System	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:00
User entered empty.	System	19 Nov 2020 18:29:27

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 23:07:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 23:07:03
Data point term sent to Coder	System	24 Feb 2021 23:06:16
User entered 'Oxycodone'	(b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'Kidney Stones'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered '5'	(b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User entered '1'	System	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User entered '1'	System	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:46:01
User entered '804 (804)'	System	24 Feb 2021 23:06:10

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Apr 2021 05:15:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 05:15:18
Data point term sent to Coder	System	29 Apr 2021 17:20:49
User entered 'Migraine Injection Treatment (Sumatriptan Injection)'	(b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered 'Migraines'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered '6'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered 'every month (QM)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User entered '1'	System	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User entered '1'	System	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:57:58
User entered '802 (802)'	System	29 Apr 2021 17:20:07

US3462364

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:40:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:05:24
User entered 'Yes (Y)'		29 Apr 2021 17:01:29

US3462364

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 May 2021 16:36:39

US3462364

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'Lithotripsy procedure'	(b) (4) (b) (4), (b) (6)	03 May 2021 16:36:39

US3462364

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	03 May 2021 16:36:39

US3462364

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:11

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	03 May 2021 18:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:36:39

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'USA-US093-2021-MRNA-1273-P301000007'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'Yes (Y)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'No (N)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'No (N)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'Yes (Y)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'No (N)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'No (N)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'No (N)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'Edward'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'Kerwin'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'US'	(b) (4) System	25 Feb 2021 19:15:56

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 19:15:56

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'USA-US093-2021-MRNA-1273-P301000007'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'Yes (Y)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'No (N)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'No (N)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'Yes (Y)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'No (N)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'No (N)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'No (N)'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'Edward'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:41
User entered 'Kerwin'	System	25 Feb 2021 19:15:22

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered 'US'	(b) (4) System	25 Feb 2021 19:15:56

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 19:15:56

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:25:43
User entered '25/Feb/2021 14:15'	(b) (4) System	25 Feb 2021 19:15:56

US3462364

Folder: SAE USA-US093-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:11

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 Mar 2021 19:25:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:56