

US3462388 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:40:53

All time stamps listed in this document are displayed in GMT

US3462388

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:42:30

Generated On: 09 Jun 2021 17:40:53

Participant ID

US3462388

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

US3462388

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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 02:01:38

Generated On: 09 Jun 2021 17:40:53

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Date of Informed Consent (<i>dd MMM yyyy</i>)	31 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 02:01:38

Generated On: 09 Jun 2021 17:40:53

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 02:01:38

Generated On: 09 Jun 2021 17:40:53

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Condition	OCCASIONAL CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
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 02:01:38

Generated On: 09 Jun 2021 17:40:53

Condition	OCCASIONAL ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Condition	TOURETTS SYNDROME
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Condition	LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
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 02:01:38

Generated On: 09 Jun 2021 17:40:53

Condition	RIGHT ANKLE BREAK WITH SURGICAL REPAIR
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Condition	PSORIASIS (FEET)
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Condition	ANTIINFLAMATORY ALLERGY (STOMACH ACHE)
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Condition	LOW BACK FUSION
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Condition	NECK FUSION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:03 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 08:03
Height (<i>xxx.x</i>)	175 cm
Weight (<i>xxx.x</i>)	80 kg
BMI (<i>xxx.x</i>)	26.12245 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 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:01:38

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:01:38

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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 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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 02:01:38

Generated On: 09 Jun 2021 17:40:53

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 109642

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 02:01:38

Generated On: 09 Jun 2021 17:40:53

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 02:01:38

Generated On: 09 Jun 2021 17:40:53

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)	31 AUG 2020
Time of assessment (00:00-23:59)	08:03 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 08:03
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 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 02:01:38

Generated On: 09 Jun 2021 17:40:53

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)	31 AUG 2020
Time of assessment (00:00-23:59)	9:38 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 9:38
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 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 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 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 02:01:38

Generated On: 09 Jun 2021 17:40:53

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 09:01 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 09:01

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 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

08:46 (24 HR)

Collection date and time (derived)

31 AUG 2020 08:46

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:50	31 AUG 2020 08:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 09:32

PC Open Date & Time

31 AUG 2020 09:21

PC Close Date & Time

31 AUG 2020 11:51

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 31 AUG 2020 13:13

PC Open Date & Time 31 AUG 2020 12:46

PC Close Date & Time 01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

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 98.2 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 01 SEP 2020 12:44

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

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

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

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

PC Time Stamp	02 SEP 2020 12:01
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

97.7 °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

03 SEP 2020 13:47

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °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	05 SEP 2020 08:30
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 SEP 2020 08:55

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:53

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 09:33

PC Open Date & Time

31 AUG 2020 09:21

PC Close Date & Time

31 AUG 2020 11:51

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

31 AUG 2020 13:14

PC Open Date & Time

31 AUG 2020 12:46

PC Close Date & Time

01 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

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

01 SEP 2020 12:44

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

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

02 SEP 2020 12:01

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

03 SEP 2020 13:47

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

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

05 SEP 2020 08:30

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

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

06 SEP 2020 08:56

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 09:33
PC Open Date & Time	31 AUG 2020 09:21
PC Close Date & Time	31 AUG 2020 11:51

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 13:15
PC Open Date & Time	31 AUG 2020 12:46
PC Close Date & Time	01 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

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 ☒

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:45
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

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 ☒

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

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 ☒

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 13:48
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

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 ☒

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 08:30
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 08:56
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3462388

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3462388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:01:39

Generated On: 09 Jun 2021 17:40:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:01:39

Generated On: 09 Jun 2021 17:40:53

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)	12 OCT 2020
Time of assessment (00:00-23:59)	08:06 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 08:06
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:01:39

Generated On: 09 Jun 2021 17:40:53

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)	12 OCT 2020
Time of assessment (00:00-23:59)	09:28 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 09:28
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3462388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:01:39

Generated On: 09 Jun 2021 17:40:53

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.

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:01:39

Generated On: 09 Jun 2021 17:40:53

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) 12 OCT 2020

What was the treatment time? (00:00-23:59) 08:53 (24 HR)

Treatment Date and Time (derived) 12 OCT 2020 08:53

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

US3462388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:01:39

Generated On: 09 Jun 2021 17:40:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

08:34 (24 HR)

Collection date and time (derived)

12 OCT 2020 08:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Collection date (dd MMM yyyy)			12 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:29	12 OCT 2020 08:29
Nasopharyngeal Swab 2	No		

US3462388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:01:39

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 09:26

PC Open Date & Time

12 OCT 2020 09:13

PC Close Date & Time

12 OCT 2020 11:43

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	12 OCT 2020 18:23
PC Open Date & Time	12 OCT 2020 12:38
PC Close Date & Time	13 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 02:43

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

15 OCT 2020 02:17

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

98.2 °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

15 OCT 2020 15:35

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

17 OCT 2020 05:22

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 07:39

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 02:54

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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

12 OCT 2020 09:26

PC Open Date & Time

12 OCT 2020 09:13

PC Close Date & Time

12 OCT 2020 11:43

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

12 OCT 2020 18:23

PC Open Date & Time

12 OCT 2020 12:38

PC Close Date & Time

13 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

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

14 OCT 2020 02:43

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

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

15 OCT 2020 02:17

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

15 OCT 2020 15:35

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

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

17 OCT 2020 05:23

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

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

18 OCT 2020 07:39

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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

19 OCT 2020 02:54

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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

No ☒

Yes ☐

PC Time stamp	12 OCT 2020 09:26
PC Open Date & Time	12 OCT 2020 09:13
PC Close Date & Time	12 OCT 2020 11:43

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

No ☒

Yes ☐

PC Time stamp	12 OCT 2020 18:23
PC Open Date & Time	12 OCT 2020 12:38
PC Close Date & Time	13 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

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 ☒

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 02:44
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

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 ☒

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 02:18
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

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 ☒

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 15:35
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

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
EAB) (1725)

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US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 05:23
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

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)

108 of 2351

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 07:40
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

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 ☒

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 02:55
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3462388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:01:38

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:01:52

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:01:52

Generated On: 09 Jun 2021 17:40:53

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) _____

US3462388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:01:52

Generated On: 09 Jun 2021 17:40:53

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.

US3462388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:01:39

Generated On: 09 Jun 2021 17:40:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 NOV 2020

Collection time (00:00-23:59)

08:00 (24 HR)

Collection date and time (derived)

02 NOV 2020 08:00

US3462388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:01:39

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 17:44:47
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

07 NOV 2020 06:46:02

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 <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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 <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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 <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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

08 APR 2021 13:11:40

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

14 APR 2021 20:44:36

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 <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	21 APR 2021 16:23:16
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

30 APR 2021 12:13:19

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 <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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAY 2021 00:01
Patient Cloud Close Date & Time	16 MAY 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 348

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

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

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

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

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	22 AUG 2021 23:59
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US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	31 OCT 2021 23:59
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US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 <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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 <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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 <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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 FEB 2022 00:01
Patient Cloud Close Date & Time	20 FEB 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 <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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 607

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

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

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

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

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

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

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUN 2022 00:01
Patient Cloud Close Date & Time	12 JUN 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	10 JUL 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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="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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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="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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	30 OCT 2022 23:59
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US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3462388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:40:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		08 APR 2021 13:11:58

US3462388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:42:31

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:42:31

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 18:20:35

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:20:35

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 18:20:35

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

PATIENT CALLED BUT NOT
CONTACTED, MESSAGE LEFT

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:20:35

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 18:20:55

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 MAR 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

PATIENT CALLED BUT NOT
CONTACTED, MESSAGE LEFT

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:20:35

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 APR 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

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 APR 2021
Time of assessment (<i>00:00-23:59</i>)	11:50 (24 HR)
Vital Signs Date and Time (derived)	08 APR 2021 11:50
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	99 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3462388

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

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.

US3462388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 APR 2021
Collection time (00:00-23:59)	11:55 (24 HR)
Collection date and time (derived)	08 APR 2021 11:55

US3462388

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462388

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:53

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"/>

US3462388

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:40:53

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3462388

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

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 00:06:17

Generated On: 09 Jun 2021 17:40:53

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

Visit date (dd MMM yyyy)	3 MAR 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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US3462388

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

Form: Unblinding

Data signed: (b) (4) 31 Mar 2021 00:06:17

Generated On: 09 Jun 2021 17:40:53

Date of updated informed consent (<i>dd MMM yyyy</i>)	3 MAR 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>)	3 MAR 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

US3462388

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 31 Mar 2021 00:06:17

Generated On: 09 Jun 2021 17:40:53

Height	175 cm
Weight	80 kg
BMI (xxx.x)	26.12245

US3462388

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 31 Mar 2021 00:06:17

Generated On: 09 Jun 2021 17:40:53

Height	175 cm
Weight	80 kg
BMI (xxx.x)	26.12245
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)	3 MAR 2021
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 09:50
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462388

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 31 Mar 2021 00:06:17

Generated On: 09 Jun 2021 17:40:53

Height	175 cm
Weight	80 kg
BMI (xxx.x)	26.12245
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)	3 MAR 2021
Time of assessment (00:00-23:59)	11:37 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 11:37
Temperature (xxx.x)	98.0 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3462388

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

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 00:06:17

Generated On: 09 Jun 2021 17:40:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 MAR 2021

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

US3462388

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

Form: Exposure

Data signed: (b) (4) 31 Mar 2021 00:06:17

Generated On: 09 Jun 2021 17:40:53

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) 3 MAR 2021

What was the treatment time? (00:00-23:59) 11:00 (24 HR)

Treatment Date and Time (derived) 3 MAR 2021 11:00

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

What was the frequency of the study treatment dosing? ONCE

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

US3462388

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 00:06:17

Generated On: 09 Jun 2021 17:40:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00-23:59)	09:35 (24 HR)
Collection date and time (derived)	3 MAR 2021 09:35

US3462388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 31 Mar 2021 00:06:17

Generated On: 09 Jun 2021 17:40:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00 - 23:59)	09:19
Collection Date and Time (derived)	3 MAR 2021 09:19

US3462388

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

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 00:06:17

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 18:20:55

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:20:55

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 APR 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

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 APR 2021
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	08 APR 2021 11:50
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 APR 2021
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	08 APR 2021 13:22
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3462388

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

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.

US3462388

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

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) 08 APR 2021

What was the treatment time? (00:00-23:59) 12:49 (24 HR)

Treatment Date and Time (derived) 08 APR 2021 12:49

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

What was the frequency of the study treatment dosing? ONCE

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

US3462388

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 00:46:16

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 20:07:05

Generated On: 09 Jun 2021 17:40:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462388

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 20:07:05

Generated On: 09 Jun 2021 17:40:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462388

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Apr 2021 20:07:05

Generated On: 09 Jun 2021 17:40:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 APR 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

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Apr 2021 20:07:05

Generated On: 09 Jun 2021 17:40:53

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) _____

US3462388

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Apr 2021 20:07:05

Generated On: 09 Jun 2021 17:40:53

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.

US3462388

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Apr 2021 20:07:05

Generated On: 09 Jun 2021 17:40:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	29 APR 2021
Collection time (<i>00:00-23:59</i>)	10:05 (24 HR)
Collection date and time (derived)	29 APR 2021 10:05

US3462388

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 20:42:30

Generated On: 09 Jun 2021 17:40:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

AEID	USA-US093-2020-MRNA-1273-P30 1000006
Adverse event	ASPIRATION PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 OCT 2020
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)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	04 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

PATIENT IS A 46 YEAR OLD
MALE WITH
HYPERCHOLESTEROLEMIA
AND DEPRESSION. ON
25SEP2020 WHILE EATING, HE
ASPIRATED ON A PIECE OF
FOOD AND HAD COUGHING
THROUGHOUT THAT DAY. HE
ALSO COUGHED THROUGH THE
NIGHT. THE NEXT MORNING,
26SEP2020, AT WORK HE HAD A
SYNCOPE EPISODE. EMS WAS
ACTIVATED AND HE WAS
EVALUATED IN THE
EMERGENCY DEPARTMENT.
CHEST IMAGING SHOWED
PULMONARY INFILTRATE AND
WAS TREATED FOR
ASPIRATION PNEUMONIA WITH
ANTIBIOTICS. HE REMAINED
IN THE HOSPITAL FOR 8 DAYS
(26SEP2020-04OCT2020). HE
ALSO HAD A HEAD CT TO
EVALUATE FOR STROKE, NONE
WAS SEEN. PATIENT
DISCHARGED 04OCT2020.
PATIENT WAS
CONSENTED/SCREENED/AND
RANDOMIZED TO STUDY
31AUG2020. HE HAD HIS FIRST
IP INJECTION ON THAT DAY.
HE DID NOT RECEIVE HIS
SECOND IP INJECTION AS HE
WAS HOSPITALIZED. WE WERE
NOTIFIED OF THESE EVENTS
07OCT2020. SAE OF
ASPIRATION PNEUMONIA NOT
RELATED TO STUDY IP.
PATIENT RECOVERED AND
PLANS TO RETURN TO
CONTINUE STUDY NEXT WEEK.

Serious Adverse Event Derived (CSA Programming Field Only)	1
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3462388

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

AEID	USA-US093-2020-MRNA-1273-P30 1000006
Adverse event	MYOCARDIAL INFARCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 SEP 2020
End time (00:00-23:59)	
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)	25 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	25 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3462388

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

SUBJECT IS A 46 YEAR OLD
MALE WITH PREVIOUSLY
REPORTED SAE OF ASPIRATION
PNEUMONIA THAT OCCURRED
25SEP2020-04OCT2020. SUBJECT
HAD NO DIAGNOSIS OF ANY
HEART RELATED CONDITIONS
AT TIME OF THIS
HOSPITALIZATION, HOWEVER,
HE DID HAVE ONGOING
SUSPICION THAT THIS EVENT
WAS HEART RELATED.
THEREFORE, SUBJECT
REACHED OUT TO A LOCAL
CARDIOLOGIST IN DECEMBER
2020. CARDIOLOGIST ORDERED
AN ANGIOGRAM BE
PERFORMED ON
APPROXIMATELY 02DEC2020.
ANGIOGRAM REVELED THAT
SUBJECT HAD SEVERE
ARTHROSCLEROSIS OF ONE OF
THE MAIN ARTERIES GOING
INTO THE HEART AND SUBJECT
REPORTED THAT
CARDIOLOGIST DIAGNOSED
EVENT ON 25SEP2020 AS ALSO
BEING MYOCARDIAL
INFARCTION. THEREFORE,
SINGLE BYPASS SURGERY WAS
SCHEDULED AND PERFORMED
ON 11DEC2020. SUBJECT
REPORTED THAT SURGERY
WAS PERFORMED WITHOUT
COMPLICATION AND SUBJECT
WAS DISCHARGED ON
APPROXIMATELY 14DEC2020.
ALL EVENT DETAILS WERE
OBTAINED VIA SUBJECT
VERBAL REPORT AT VISIT 4.

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

AEID	USA-US093-2020-MRNA-1273-P30 1000006
Adverse event	SEVERE ARTHROSCLEROSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	11 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	14 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

SUBJECT IS A 46 YEAR OLD
MALE WITH PREVIOUSLY
REPORTED SAE OF ASPIRATION
PNEUMONIA THAT OCCURRED
25SEP2020-04OCT2020. SUBJECT
HAD NO DIAGNOSIS OF ANY
HEART RELATED CONDITIONS
AT TIME OF THIS
HOSPITALIZATION, HOWEVER,
HE DID HAVE ONGOING
SUSPICION THAT THIS EVENT
WAS HEART RELATED.
THEREFORE, SUBJECT
REACHED OUT TO A LOCAL
CARDIOLOGIST IN DECEMBER
2020. CARDIOLOGIST ORDERED
AN ANGIOGRAM BE
PERFORMED ON
APPROXIMATELY 02DEC2020.
ANGIOGRAM REVELED THAT
SUBJECT HAD SEVERE
ARTHROSCLEROSIS OF ONE OF
THE MAIN ARTERIES GOING
INTO THE HEART AND SUBJECT
REPORTED THAT
CARDIOLOGIST DIAGNOSED
EVENT ON 25SEP2020 AS ALSO
BEING MYOCARDIAL
INFARCTION. THEREFORE,
SINGLE BYPASS SURGERY WAS
SCHEDULED AND PERFORMED
ON 11DEC2020. SUBJECT
REPORTED THAT SURGERY
WAS PERFORMED WITHOUT
COMPLICATION AND SUBJECT
WAS DISCHARGED ON
APPROXIMATELY 14DEC2020.
ALL EVENT DETAILS WERE
OBTAINED VIA SUBJECT
VERBAL REPORT AT VISIT 4.

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

AEID	USA-US093-2020-MRNA-1273-P30 1000006
Adverse event	POST SURGICAL PERICARDITIS SECONDARY TO CORONARY BYPASS SURGERY
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)	28 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	28 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	30 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

SUBJECT IS A 46 YEAR OLD
MALE WITH PREVIOUSLY
REPORTED SAE OF ASPIRATION
PNEUMONIA THAT OCCURRED
25SEP2020-04OCT2020. SUBJECT
HAD NO DIAGNOSIS OF ANY
HEART RELATED CONDITIONS
AT TIME OF THIS
HOSPITALIZATION, HOWEVER,
HE DID HAVE ONGOING
SUSPICION THAT THIS EVENT
WAS HEART RELATED.
THEREFORE, SUBJECT
REACHED OUT TO A LOCAL
CARDIOLOGIST IN DECEMBER
2020. CARDIOLOGIST ORDERED
AN ANGIOGRAM BE
PERFORMED ON
APPROXIMATELY 02DEC2020.
ANGIOGRAM REVELED THAT
SUBJECT HAD SEVERE
ARTHROSCLEROSIS OF ONE OF
THE MAIN ARTERIES GOING
INTO THE HEART AND SUBJECT
REPORTED THAT
CARDIOLOGIST DIAGNOSED
EVENT ON 25SEP2020 AS ALSO
BEING MYOCARDIAL
INFARCTION. THEREFORE,
SINGLE BYPASS SURGERY WAS
SCHEDULED AND PERFORMED
ON 11DEC2020. SUBJECT
REPORTED THAT SURGERY
WAS PERFORMED WITHOUT
COMPLICATION AND SUBJECT

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WAS DISCHARGED ON
APPROXIMATELY 14DEC2020.
ALL EVENT DETAILS WERE
OBTAINED VIA SUBJECT
VERBAL REPORT AT VISIT 4.

FOLLOWING SURGERY,
SUBJECT HAD CONTINUED
SHORTNESS OF BREATH AND
THEREFORE, WENT TO THE ER
ON 28DEC2020 AND WAS
DIAGNOSED WITH
POST-SURGICAL PERICARDITIS
AND PLEURAL EFFUSION BOTH
SECONDARY TO CORONARY
BYPASS SURGERY . SUBJECT
REPORTED THAT FLUID WAS
DRAINED FROM HEART AND
FROM LUNGS. SUBJECT
STATED THAT PROCEDURES
WERE PERFORMED WITHOUT
COMPLICATION AND SUBJECT
WAS DISCHARGED ON
APPROXIMATELY 30DEC2020.

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

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Folder: Adverse Events

Form: Adverse Events (5)

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AEID	USA-US093-2020-MRNA-1273-P30 1000006
Adverse event	POST SURGICAL PLEURAL EFFUSION
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)	28 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	28 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	30 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Apr 2021 21:14:00

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FOLLOWING SURGERY,
SUBJECT HAD CONTINUED
SHORTNESS OF BREATH AND
THEREFORE, WENT TO THE ER
ON 28DEC2020 AND WAS
DIAGNOSED WITH
POST-SURGICAL PERICARDITIS
AND PLEURAL EFFUSION BOTH
SECONDARY TO CORONARY
BYPASS SURGERY . SUBJECT
REPORTED THAT FLUID WAS
DRAINED FROM HEART AND
FROM LUNGS. SUBJECT
STATED THAT PROCEDURES
WERE PERFORMED WITHOUT
COMPLICATION AND SUBJECT
WAS DISCHARGED ON
APPROXIMATELY 30DEC2020.

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 15 Apr 2021 21:14:00

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AEID	USA-US093-2020-MRNA-1273-P30 1000006
Adverse event	POST-SURGICAL PERICARDITIS SECONDARY TO CORONARY BYPASS SURGERY
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)	14 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	14 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	20 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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	Unknown	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
<hr/>		
Other action taken (check all that apply)		
None		False
Concomitant Medication		False
Concomitant Procedure		True
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input checked="" type="radio"/>
	Recovered/Resolved with Sequelae	<input type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		
<hr/>		

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

FOLLOWING SURGERY, SUBJECT HAD CONTINUED SHORTNESS OF BREATH AND THEREFORE, WENT TO THE ER ON 28DEC2020 AND WAS DIAGNOSED WITH POST-SURGICAL PERICARDITIS AND PLEURAL EFFUSION BOTH SECONDARY TO CORONARY BYPASS SURGERY . SUBJECT REPORTED THAT FLUID WAS DRAINED FROM HEART AND FROM LUNGS. SUBJECT STATED THAT PROCEDURES WERE PERFORMED WITHOUT COMPLICATION AND SUBJECT WAS DISCHARGED ON APPROXIMATELY 30DEC2020.

SUBJECT CONTINUED TO HAVE SHORTNESS OF BREATH AND THEREFORE, WENT BACK TO ER ON APPROXIMATELY 14JAN2021. SUBJECT ADMITTED AGAIN DUE TO ONGOING POST-SURGICAL PERICARDITIS AND PLEURAL EFFUSION. SUBJECT HAD PERICARDIAL WINDOW PROCEDURE PERFORMED. PROCEDURE WAS PERFORMED WITHOUT COMPLICATION AND SUBJECT WAS DISCHARGED ON APPROXIMATELY 20JAN2021.

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 15 Apr 2021 21:14:00

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AEID	USA-US093-2020-MRNA-1273-P30 1000006
Adverse event	POST SURGICAL PERICARDITIS SECONDARY TO CORONARY BYPASS SURGERY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	30 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
<hr/>		
Persistent or significant disability or incapacity		False
<hr/>		
Congenital anomaly or birth defect		False
<hr/>		
Other medically important event		False
<hr/>		
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
<hr/>		
Other action taken (check all that apply)		
<hr/>		
None		False
<hr/>		
Concomitant Medication		False
<hr/>		
Concomitant Procedure		True
<hr/>		
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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		
<hr/>		

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 15 Apr 2021 21:14:00

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SUBJECT CONTINUED TO HAVE
SHORTNESS OF BREATH AND
THEREFORE, WENT BACK TO
ER ON APPROXIMATELY
14JAN2021. SUBJECT ADMITTED
AGAIN DUE TO ONGOING
POST-SURGICAL PERICARDITIS
AND PLEURAL EFFUSION.
SUBJECT HAD PERICARDIAL
WINDOW PROCEDURE
PERFORMED. PROCEDURE WAS
PERFORMED WITHOUT
COMPLICATION AND SUBJECT
WAS DISCHARGED ON
APPROXIMATELY 20JAN2021.
FOLLOWING THIS PROCEDURE,
SUBJECT CONTINUED TO HAVE
SHORTNESS OF BREATH AND
RETURNED FOR SECOND
PERICARDIAL WINDOW
PROCEDURE ON
APPROXIMATELY 26JAN2021.
SUBJECT REPORTED THAT
PROCEDURE WAS PERFORMED
WITHOUT COMPLICATION AND
SUBJECT WAS DISCHARGED ON
APPROXIMATELY 30JAN2021.
ALL HOSPITALIZATION
DETAILS WERE OBTAINED VIA
SUBJECT VERBAL REPORT. WE
WILL CONFIRM DETAILS
FOLLOWING RECEIPT OF
HOSPITAL RECORDS.

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 15 Apr 2021 21:14:00

Generated On: 09 Jun 2021 17:40:53

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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Form: Adverse Events (8)

Data signed: (b) (4) 15 Apr 2021 21:14:00

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Persistent or significant disability or incapacity	
Congenital anomaly or birth defect	
Other medically important event	
Relationship to investigational product	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Relationship to Study Procedure	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Action taken with investigational product	None <input type="checkbox"/>
	Dose Delayed <input type="checkbox"/>
	Investigational Product <input type="checkbox"/>
	Withdrawn <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal <input type="checkbox"/>
	Not Recovered/Not Resolved <input type="checkbox"/>
	Recovered/Resolved <input type="checkbox"/>
	Recovered/Resolved with <input type="checkbox"/>
	Sequelae <input type="checkbox"/>
	Recovering/Resolving <input type="checkbox"/>
	Unknown <input type="checkbox"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	
Medically Attended AE Derived (CSA Programming Field Only)	
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 20:42:30

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Name of Medication NORCO (5/325)

Prophylaxis Yes ☐
No ☒

Indication LOWER BACK PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 20:42:30

Generated On: 09 Jun 2021 17:40:53

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication TOURETTS SYNDROME

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 20:42:30

Generated On: 09 Jun 2021 17:40:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 20:42:30

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Name of Medication VALIUM

Prophylaxis Yes ☐
No ☒

Indication TOURETTES SYNDROME

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 20:42:30

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 20:42:30

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Name of Medication NEXIUM

Prophylaxis Yes ☐
No ☒

Indication OCCASIONAL ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 20:42:30

Generated On: 09 Jun 2021 17:40:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 20:42:30

Generated On: 09 Jun 2021 17:40:53

Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

406 of 2351

EAB) (1725)

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 20:42:30

Generated On: 09 Jun 2021 17:40:53

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 20:42:30

Generated On: 09 Jun 2021 17:40:53

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

408 of 2351

EAB) (1725)

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 20:42:30

Generated On: 09 Jun 2021 17:40:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Apr 2021 05:05:29

Generated On: 09 Jun 2021 17:40:53

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Apr 2021 21:14:01

Generated On: 09 Jun 2021 17:40:53

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 DEC 2020	ANGIOGRAM	Adverse Event	
11 DEC 2020	SINGLE BYPASS SURGERY	Adverse Event	
26 JAN 2021	FLUID DRAINING FROM HEART AND LUNGS	Adverse Event	

US3462388

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:40:53

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

US3462388

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:40:53

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 ☐

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 22:56:40

Generated On: 09 Jun 2021 17:40:53

SAEID	USA-US093-2020-MRNA-1273-P301000006
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 22:56:40

Generated On: 09 Jun 2021 17:40:53

SAEID	USA-US093-2020-MRNA-1273-P301000006
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/OCT/2020 13:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 22:56:40

Generated On: 09 Jun 2021 17:40:53

SAEID	USA-US093-2020-MRNA-1273-P301000006
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/MAR/2021 14:19
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

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 22:56:40

Generated On: 09 Jun 2021 17:40:53

SAEID	USA-US093-2020-MRNA-1273-P301000006
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/MAR/2021 14:40
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

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 22:56:40

Generated On: 09 Jun 2021 17:40:53

SAEID	USA-US093-2020-MRNA-1273-P301000006
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/APR/2021 14:06
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

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 22:56:40

Generated On: 09 Jun 2021 17:40:53

SAEID	USA-US093-2020-MRNA-1273-P301000006
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/APR/2021 16:02
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

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 22:56:40

Generated On: 09 Jun 2021 17:40:53

SAEID	USA-US093-2020-MRNA-1273-P301000006
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/APR/2021 13:18
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

US3462388 (Prod: Crisor, LLC)

US3462388

Form: Participant Creation

Generated On: 09 Jun 2021 17:40:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User entered 'US3462388'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:14:29

US3462388

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:13:49

US3462388

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:14:30

US3462388

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:13:49

US3462388

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'SCRN'	System	31 Aug 2020 16:13:49

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered (b) (6) 1974'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:14:31

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '46'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'YEARS'	System	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '46'	System	31 Aug 2020 16:14:12

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Male (M)'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:24:33

US3462388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:14:12

US3462388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Aug 2020'	System	31 Aug 2020 16:14:12

US3462388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2020'	System	31 Aug 2020 16:14:12

US3462388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:14:12

US3462388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:14:12

US3462388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:14:12

US3462388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:14:12

US3462388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:14:12

US3462388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:14:30

US3462388

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'I'	System	31 Aug 2020 16:14:22

US3462388

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:14:22

US3462388

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:40:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 01:24:49

US3462388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:26:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:26:42
Data point term sent to Coder	System	01 Sep 2020 01:26:03
User entered 'OCCASIONAL CONSTIPATION'	(b) (4), (b) (6)	01 Sep 2020 01:25:09

US3462388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 01:25:09

US3462388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:25:09

US3462388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 01:25:09

US3462388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:25:09

US3462388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:25:09

US3462388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2005'	System	01 Sep 2020 01:25:09

US3462388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2005'	System	01 Sep 2020 01:25:09

US3462388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:25:09

US3462388

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:25:09

US3462388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:26:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:26:42
Data point term sent to Coder	System	01 Sep 2020 01:26:05
User entered 'OCCASIONAL ACID REFLUX'	(b) (4), (b) (6)	01 Sep 2020 01:25:26

US3462388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 01:25:26

US3462388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:25:26

US3462388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 01:25:26

US3462388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:25:26

US3462388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:25:26

US3462388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2005'	System	01 Sep 2020 01:25:26

US3462388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2005'	System	01 Sep 2020 01:25:26

US3462388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:25:26

US3462388

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:25:26

US3462388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Neurological disorders congenital, HLT: Neurological disorders congenital NEC, PT: Tourette's disorder, LLT: Tourette's syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 08:41:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 08:41:49
Data point term sent to Coder	System	01 Sep 2020 01:26:05
User entered 'TOURETTS SYNDROME'	(b) (4), (b) (6)	01 Sep 2020 01:25:40

US3462388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 1990'	(b) (4), (b) (6)	01 Sep 2020 01:25:40

US3462388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:25:40

US3462388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 01:25:40

US3462388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:25:40

US3462388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:25:40

US3462388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 1990'	System	01 Sep 2020 01:25:40

US3462388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '1990'	System	01 Sep 2020 01:25:40

US3462388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:25:40

US3462388

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:25:40

US3462388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:26:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:26:42
Data point term sent to Coder	System	01 Sep 2020 01:26:03
User entered 'HYPERCHOLESTEROLEMIA'	(b) (4), (b) (6)	01 Sep 2020 01:25:58

US3462388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:25:58

US3462388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:25:58

US3462388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 01:25:58

US3462388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:25:58

US3462388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:25:58

US3462388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2019'	System	01 Sep 2020 01:25:58

US3462388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2019'	System	01 Sep 2020 01:25:58

US3462388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:25:58

US3462388

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:25:58

US3462388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:27:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:27:43
Data point term sent to Coder	System	01 Sep 2020 01:27:08
User entered 'LOWER BACK PAIN'	(b) (4), (b) (6)	01 Sep 2020 01:26:09

US3462388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:26:09

US3462388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:26:09

US3462388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User closed query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of LOW BACK FUSION was performed in 2017. Please review and update if appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of LOW BACK FUSION was performed in 2017. Please review and update if appropriate. Otherwise, clarify.' answered with 'ongoing' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:18:59
User opened query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of LOW BACK FUSION was performed in 2017. Please review and update if appropriate. Otherwise, clarify.' (Site from DM).		21 Oct 2020 17:28:53
User entered 'Yes (Y)'		23 Sep 2020 19:31:31
		01 Sep 2020 01:26:09

US3462388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:26:09

US3462388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:26:09

US3462388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2015'	System	01 Sep 2020 01:26:09

US3462388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2015'	System	01 Sep 2020 01:26:09

US3462388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:26:09

US3462388

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:26:09

US3462388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Ankle fracture - version MedDRA\23.0.	Coder Import (b) (4)	16 Dec 2020 12:43:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Dec 2020 12:43:56
Data point term sent to Coder	System	16 Dec 2020 11:57:26
Query ' DM-Coding: please split this term into 2 separate entries. 1) RIGHT ANKLE BREAK 2)SURGICAL REPAIRRIGHT ANKLE BREAK. One record per line. Please update this term in accordance with your answer.' canceled (Site from System).	Coder Import (b) (4)	16 Dec 2020 11:57:17
User opened query ' DM-Coding: please split this term into 2 separate entries. 1) RIGHT ANKLE BREAK 2)SURGICAL REPAIRRIGHT ANKLE BREAK. One record per line. Please update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4)	19 Nov 2020 11:11:57
Data point term sent to Coder	System	01 Sep 2020 01:27:06
User entered 'RIGHT ANKLE BREAK WITH SURGICAL REPAIR'	(b) (4), (b) (6)	01 Sep 2020 01:26:47

US3462388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2011'	(b) (4), (b) (6)	01 Sep 2020 01:26:47

US3462388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:26:47

US3462388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:26:47

US3462388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:26:47

US3462388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:26:47

US3462388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2011'	System	01 Sep 2020 01:26:47

US3462388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2011'	System	01 Sep 2020 01:26:47

US3462388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2011'	System	01 Sep 2020 01:26:47

US3462388

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2011'	System	01 Sep 2020 01:26:47

US3462388

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 08:30:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 08:30:43
Data point term sent to Coder	System	01 Sep 2020 01:27:08
User entered 'PSORIASIS (FEET)'	(b) (4), (b) (6)	01 Sep 2020 01:27:07

US3462388

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 01:27:07

US3462388

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:27:07

US3462388

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:27:07

US3462388

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:27:07

US3462388

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:27:07

US3462388

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2005'	System	01 Sep 2020 01:27:07

US3462388

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2005'	System	01 Sep 2020 01:27:07

US3462388

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:27:07

US3462388

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:27:07

US3462388

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User coded data point as SOC: Psychiatric disorders, HLGTT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:28:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:28:35
Data point term sent to Coder	System	01 Sep 2020 01:28:09
User entered 'DEPRESSION'	(b) (4), (b) (6)	01 Sep 2020 01:27:27

US3462388

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:27:27

US3462388

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:27:27

US3462388

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 01:27:27

US3462388

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:27:27

US3462388

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:27:27

US3462388

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2015'	System	01 Sep 2020 01:27:27

US3462388

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2015'	System	01 Sep 2020 01:27:27

US3462388

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:27:27

US3462388

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:27:27

US3462388

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
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: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 22:49:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 22:49:41
Data point term sent to Coder	System	01 Sep 2020 01:28:09
User entered 'ANTIINFLAMATORY ALLERGY (STOMACH ACHE)'	(b) (4), (b) (6)	01 Sep 2020 01:27:58

US3462388

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 01:27:58

US3462388

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:27:58

US3462388

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:27:58

US3462388

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:27:58

US3462388

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:27:58

US3462388

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2005'	System	01 Sep 2020 01:27:58

US3462388

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2005'	System	01 Sep 2020 01:27:58

US3462388

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:27:58

US3462388

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered empty.	System	01 Sep 2020 01:27:58

US3462388

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Spinal fusion - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 07:49:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 07:49:45
Data point term sent to Coder	System	01 Sep 2020 01:29:09
User entered 'LOW BACK FUSION'	(b) (4), (b) (6)	01 Sep 2020 01:28:18

US3462388

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2017'	(b) (4), (b) (6)	01 Sep 2020 01:28:18

US3462388

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:28:18

US3462388

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:28:18

US3462388

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2017'	(b) (4), (b) (6)	01 Sep 2020 01:28:18

US3462388

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:28:18

US3462388

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2017'	System	01 Sep 2020 01:28:18

US3462388

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2017'	System	01 Sep 2020 01:28:18

US3462388

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2017'	System	01 Sep 2020 01:28:18

US3462388

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2017'	System	01 Sep 2020 01:28:18

US3462388

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:30:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 01:30:39
Data point term sent to Coder	System	01 Sep 2020 01:29:10
User entered 'NECK FUSION'	(b) (4), (b) (6)	01 Sep 2020 01:28:34

US3462388

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2018'	(b) (4), (b) (6)	01 Sep 2020 01:28:34

US3462388

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:28:34

US3462388

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:28:34

US3462388

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'UN UNK 2018'	(b) (4), (b) (6)	01 Sep 2020 01:28:34

US3462388

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:28:34

US3462388

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2018'	System	01 Sep 2020 01:28:34

US3462388

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2018'	System	01 Sep 2020 01:28:34

US3462388

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'Jan 2018'	System	01 Sep 2020 01:28:34

US3462388

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '2018'	System	01 Sep 2020 01:28:34

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '08:03'	(b) (4), (b) (6)	01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '31 Aug 2020 08:03'	System	01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '175' cm	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:29:30
DataPoint set to visible.	System	31 Aug 2020 16:14:22

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '80' kg	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:29:30
DataPoint set to visible.	System	31 Aug 2020 16:14:22

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered '26.12245'	System	01 Sep 2020 01:29:30
DataPoint set to visible.	System	31 Aug 2020 16:14:22

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'kg/m2'	System	01 Sep 2020 01:29:30
DataPoint set to visible.	System	31 Aug 2020 16:14:22

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:22:13
User entered '97.5' F		01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:22:13
User entered 'Other (Other)'		01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:22:13
User entered 'TYMPANIC'		01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:22:13
User entered '68'		01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'bpm'	System	01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:22:13
User entered '12'		01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'breaths/min'	System	01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:22:13
User entered '111'		01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'mmHg'	System	01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:22:13
User entered '77'		01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User entered 'mmHg'	System	01 Sep 2020 01:29:30

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26

US3462388

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26

US3462388

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 01:29:56

US3462388

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:29:56

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 01:31:42

US3462388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 01:32:09

US3462388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:32:09

US3462388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[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 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:32:09

US3462388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'VISIT1'	System	01 Sep 2020 01:32:09

US3462388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:35:38

US3462388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:53

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '109642'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:35:38

US3462388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:35:38

US3462388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:53

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 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:32:27

US3462388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:53

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 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:32:27

US3462388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:53

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:32:27

US3462388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:32:27

US3462388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 01:32:27

US3462388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:53

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 03:31:57
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:50:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:42:45

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User closed query 'Per CDM re-query: Height and Weight are blank, please record as ND per the CCG's.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:46:42
Query 'Per CDM re-query: Height and Weight are blank, please record as ND per the CCG's.' answered with 'UPDATED' (Site from DM).		03 Nov 2020 01:22:41
User entered missing code ND - Not Done; reason for change Data Entry Error		03 Nov 2020 01:22:33
User opened query 'Per CDM re-query: Height and Weight are blank, please record as ND per the CCG's.' (Site from DM).		02 Nov 2020 10:44:22
User closed query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).		02 Nov 2020 10:44:22
Query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' answered with 'updated' (Site from DM).		21 Oct 2020 17:29:24
User entered empty; reason for change Data Entry Error		21 Oct 2020 17:29:19
User opened query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).		16 Oct 2020 12:23:59
User entered '175' cm		01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:22:33
User entered empty; reason for change Data Entry Error		21 Oct 2020 17:29:19
User entered '80' kg		01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User closed query 'Per CDM re-query: Height and Weight are blank, please record as ND per the CCG's.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:46:42
Query 'Per CDM re-query: Height and Weight are blank, please record as ND per the CCG's.' answered with 'UPDATED' (Site from DM).		03 Nov 2020 01:22:41
User entered missing code ND - Not Done; reason for change Data Entry Error		03 Nov 2020 01:22:33
User opened query 'Per CDM re-query: Height and Weight are blank, please record as ND per the CCG's.' (Site from DM).		02 Nov 2020 10:44:22
User closed query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).		02 Nov 2020 10:44:22
Query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' answered with 'updated' (Site from DM).		21 Oct 2020 17:29:24
User entered empty; reason for change Data Entry Error		21 Oct 2020 17:29:19
User opened query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).		16 Oct 2020 12:23:59
User entered '175' cm		01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:22:33
User entered empty; reason for change Data Entry Error		21 Oct 2020 17:29:19
User entered '80' kg		01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User accepted default value 'Pre-Dose (PREDOSE)'		01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '08:03'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '31 Aug 2020 08:03'	System	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '97.5' F	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'TYMPANIC'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '68'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'bpm'	System	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '12'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'breaths/min'	System	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '111'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'mmHg'	System	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '77'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'mmHg'	System	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User closed query 'Per CDM re-query: Height and Weight are blank, please record as ND per the CCG's.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:46:42
Query 'Per CDM re-query: Height and Weight are blank, please record as ND per the CCG's.' answered with 'UPDATED' (Site from DM).		03 Nov 2020 01:22:41
User entered missing code ND - Not Done; reason for change Data Entry Error		03 Nov 2020 01:22:33
User opened query 'Per CDM re-query: Height and Weight are blank, please record as ND per the CCG's.' (Site from DM).		02 Nov 2020 10:44:22
User closed query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).		02 Nov 2020 10:44:22
Query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' answered with 'updated' (Site from DM).		21 Oct 2020 17:29:24
User entered empty; reason for change Data Entry Error		21 Oct 2020 17:29:19
User opened query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).		16 Oct 2020 12:23:59
User entered '175' cm		01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:22:33
User entered empty; reason for change Data Entry Error		21 Oct 2020 17:29:19
User entered '80' kg		01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User accepted default value 'Post-Dose (POSTDOSE)'		01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '9:38'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '31 Aug 2020 9:38'	System	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '97.7' F	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'TYMPANIC'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '64'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'bpm'	System	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '12'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'breaths/min'	System	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '109'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'mmHg'	System	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '66'	(b) (4), (b) (6)	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'mmHg'	System	01 Sep 2020 01:33:47

US3462388

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:33:55

US3462388

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:33:55

US3462388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:15:35

US3462388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:15:35

US3462388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

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 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:15:35

US3462388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 16:15:35

US3462388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:15:35

US3462388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '09:01'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:15:35

US3462388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '31 Aug 2020 09:01'	System	31 Aug 2020 16:15:35

US3462388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:15:35

US3462388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'ONCE'	System	31 Aug 2020 16:15:35

US3462388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 16:15:35

US3462388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:34:11

US3462388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:34:11

US3462388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '08:46'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:34:11

US3462388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '31 Aug 2020 08:46'	System	01 Sep 2020 01:34:11

US3462388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:34:25

US3462388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		01 Sep 2020 01:34:25

US3462388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:34:25

US3462388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '08:50'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:34:25

US3462388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '31 Aug 2020 08:50'	System	01 Sep 2020 01:34:25

US3462388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		01 Sep 2020 01:34:25

US3462388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 03:32:14
User entered 'Yes (Y)'		01 Sep 2020 01:34:25

US3462388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 03:32:14
User entered '08:50'		01 Sep 2020 01:34:25

US3462388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered empty.	System	13 Oct 2020 03:32:14
User entered '31 Aug 2020 08:50'	System	01 Sep 2020 01:34:25

US3462388

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:34:28

US3462388

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'I'	System	01 Sep 2020 01:34:28

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:31:29', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '7066b195-0891-42fe-beff-e4825f639538'	System	31 Aug 2020 16:35:25
User entered 'Yes (Y)'	System	31 Aug 2020 16:35:25

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:31:50', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '7066b195-0891-42fe-beff-e4825f639538'	System	31 Aug 2020 16:35:25
User entered '97.7'	System	31 Aug 2020 16:35:25

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:32:03', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '7066b195-0891-42fe-beff-e4825f639538'	System	31 Aug 2020 16:35:25
User entered 'No (N)'	System	31 Aug 2020 16:35:25

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:32:14', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '7066b195-0891-42fe-beff-e4825f639538'	System	31 Aug 2020 16:35:25
User entered '31 Aug 2020 09:32'	System	31 Aug 2020 16:35:25

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '31 Aug 2020 09:21'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '31 Aug 2020 11:51'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:12:20', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '8e604fbb-5d21-46e0-8f35-bd13f4b4db3f' User entered 'Yes (Y)'	System	31 Aug 2020 20:14:53
	System	31 Aug 2020 20:14:53

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:12:36', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '8e604fbb-5d21-46e0-8f35-bd13f4b4db3f' User entered '97.6'	System	31 Aug 2020 20:14:53
	System	31 Aug 2020 20:14:53

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:12:42', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '8e604fbb-5d21-46e0-8f35-bd13f4b4db3f' User entered 'Yes (Y)'	System	31 Aug 2020 20:14:53
	System	31 Aug 2020 20:14:53

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
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 'This was put in error. Patient did not use pain meds. due to pain from vaccine but underlying medical history.' (Site from System).		10 Sep 2020 10:44:49
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 20:14:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:12:57', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '8e604fbb-5d21-46e0-8f35-bd13f4b4db3f'	System	31 Aug 2020 20:14:53
User entered '1'	System	31 Aug 2020 20:14:53

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:12:57', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '8e604fbb-5d21-46e0-8f35-bd13f4b4db3f' User entered '0'	System	31 Aug 2020 20:14:53
	System	31 Aug 2020 20:14:53

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:13:26', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '8e604fbb-5d21-46e0-8f35-bd13f4b4db3f' User entered '31 Aug 2020 13:13'	System	31 Aug 2020 20:14:53
	System	31 Aug 2020 20:14:53

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '31 Aug 2020 12:46'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 2'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:43:36', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '480c509e-7044-48f4-ab8a-8ebe4ea6c773' User entered 'Yes (Y)'	System	01 Sep 2020 19:44:10
	System	01 Sep 2020 19:44:10

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:43:44', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '480c509e-7044-48f4-ab8a-8ebe4ea6c773' User entered '98.2'	System	01 Sep 2020 19:44:10
	System	01 Sep 2020 19:44:10

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:43:50', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '480c509e-7044-48f4-ab8a-8ebe4ea6c773'	System	01 Sep 2020 19:44:10
User entered 'Yes (Y)'	System	01 Sep 2020 19:44:10

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
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 'This was put in error. Patient did not use pain meds. due to pain from vaccine but underlying medical history.' (Site from System).		10 Sep 2020 10:44:54
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	09 Sep 2020 21:06:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:43:57', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '480c509e-7044-48f4-ab8a-8ebe4ea6c773'	System	01 Sep 2020 19:44:10
User entered '1'	System	01 Sep 2020 19:44:10

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:43:57', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '480c509e-7044-48f4-ab8a-8ebe4ea6c773' User entered '0'	System	01 Sep 2020 19:44:10
	System	01 Sep 2020 19:44:10

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:08', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '480c509e-7044-48f4-ab8a-8ebe4ea6c773'	System	01 Sep 2020 19:44:10
User entered '01 Sep 2020 12:44'	System	01 Sep 2020 19:44:10

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 3'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:00:29', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4730f2ca-7a6d-497f-a68a-e4faaaf2b106'	System	02 Sep 2020 19:01:17
User entered 'Yes (Y)'	System	02 Sep 2020 19:01:17

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:00:34', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4730f2ca-7a6d-497f-a68a-e4faaaf2b106'	System	02 Sep 2020 19:01:17
User entered '98.6'	System	02 Sep 2020 19:01:17

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:00:38', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4730f2ca-7a6d-497f-a68a-e4faaaf2b106'	System	02 Sep 2020 19:01:17
User entered 'Yes (Y)'	System	02 Sep 2020 19:01:17

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
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 'This was put in error. Patient did not use pain meds. due to pain from vaccine but underlying medical history.' (Site from System).		10 Sep 2020 10:45:01
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	09 Sep 2020 21:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:10', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4730f2ca-7a6d-497f-a68a-e4faaf2b106'	System	02 Sep 2020 19:01:17
User entered '1'	System	02 Sep 2020 19:01:17

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:10', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4730f2ca-7a6d-497f-a68a-e4faaaf2b106'	System	02 Sep 2020 19:01:17
User entered '0'	System	02 Sep 2020 19:01:17

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:15', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4730f2ca-7a6d-497f-a68a-e4faaf2b106'	System	02 Sep 2020 19:01:17
User entered '02 Sep 2020 12:01'	System	02 Sep 2020 19:01:17

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 4'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:46:49', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '95fcb492-96a1-4124-8723-2c5f04fcd85a' User entered 'Yes (Y)'	System	03 Sep 2020 20:47:13
	System	03 Sep 2020 20:47:13

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:46:58', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '95fcb492-96a1-4124-8723-2c5f04fcd85a' User entered '97.7'	System	03 Sep 2020 20:47:13
	System	03 Sep 2020 20:47:13

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:03', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '95fcb492-96a1-4124-8723-2c5f04fcd85a'	System	03 Sep 2020 20:47:13
User entered 'Yes (Y)'	System	03 Sep 2020 20:47:13

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
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 'This was put in error. Patient did not use pain meds. due to pain from vaccine but underlying medical history.' (Site from System).		10 Sep 2020 10:45:05
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	03 Sep 2020 20:47:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:06', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '95fcb492-96a1-4124-8723-2c5f04fcd85a'	System	03 Sep 2020 20:47:13
User entered '1'	System	03 Sep 2020 20:47:13

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:06', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '95fcb492-96a1-4124-8723-2c5f04fcd85a' User entered '0'	System	03 Sep 2020 20:47:13
	System	03 Sep 2020 20:47:13

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:09', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '95fcb492-96a1-4124-8723-2c5f04fcd85a'	System	03 Sep 2020 20:47:13
User entered '03 Sep 2020 13:47'	System	03 Sep 2020 20:47:13

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 5'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:29:37', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4592a2f7-5ef1-4e01-a731-010456ee89ae' User entered 'Yes (Y)'	System	05 Sep 2020 15:30:05
	System	05 Sep 2020 15:30:05

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:29:46', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4592a2f7-5ef1-4e01-a731-010456ee89ae' User entered '97.9'	System	05 Sep 2020 15:30:05
	System	05 Sep 2020 15:30:05

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:29:49', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4592a2f7-5ef1-4e01-a731-010456ee89ae'	System	05 Sep 2020 15:30:05
User entered 'Yes (Y)'	System	05 Sep 2020 15:30:05

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
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 'This was put in error. Patient did not use pain meds. due to pain from vaccine but underlying medical history.' (Site from System).		10 Sep 2020 10:45:09
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	05 Sep 2020 15:30:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:29:58', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4592a2f7-5ef1-4e01-a731-010456ee89ae'	System	05 Sep 2020 15:30:05
User entered '1'	System	05 Sep 2020 15:30:05

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:29:58', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4592a2f7-5ef1-4e01-a731-010456ee89ae' User entered '0'	System	05 Sep 2020 15:30:05
	System	05 Sep 2020 15:30:05

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:01', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '4592a2f7-5ef1-4e01-a731-010456ee89ae'	System	05 Sep 2020 15:30:05
User entered '05 Sep 2020 08:30'	System	05 Sep 2020 15:30:05

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 6'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:55:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'f8f445b0-9d40-4475-91d4-0337f3ab97ec' User entered 'Yes (Y)'	System	06 Sep 2020 15:55:54
	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:55:34', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'f8f445b0-9d40-4475-91d4-0337f3ab97ec' User entered '98.1'	System	06 Sep 2020 15:55:54
	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:55:39', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'f8f445b0-9d40-4475-91d4-0337f3ab97ec' User entered 'Yes (Y)'	System	06 Sep 2020 15:55:54
	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
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 'This was put in error. Patient did not use pain meds. due to pain from vaccine but underlying medical history.' (Site from System).		10 Sep 2020 10:45:13
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	06 Sep 2020 15:55:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:55:44', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'f8f445b0-9d40-4475-91d4-0337f3ab97ec'	System	06 Sep 2020 15:55:54
User entered '1'	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:55:44', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'f8f445b0-9d40-4475-91d4-0337f3ab97ec' User entered '0'	System	06 Sep 2020 15:55:54
	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:55:49', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'f8f445b0-9d40-4475-91d4-0337f3ab97ec'	System	06 Sep 2020 15:55:54
User entered '06 Sep 2020 08:55'	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 7'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	06 Sep 2020 15:55:54
User entered 'Day 8'	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:32:33', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '62583812-269c-4570-b577-724d74501ae5' User entered 'None (1)'	System	31 Aug 2020 16:35:35
	System	31 Aug 2020 16:35:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:32:37', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '62583812-269c-4570-b577-724d74501ae5'	System	31 Aug 2020 16:35:35
User entered 'No (N)'	System	31 Aug 2020 16:35:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:32:41', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '62583812-269c-4570-b577-724d74501ae5' User entered 'No (N)'	System	31 Aug 2020 16:35:35
	System	31 Aug 2020 16:35:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:32:59', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '62583812-269c-4570-b577-724d74501ae5' User entered 'None (1)'	System	31 Aug 2020 16:35:35
	System	31 Aug 2020 16:35:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:33:04', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '62583812-269c-4570-b577-724d74501ae5' User entered '31 Aug 2020 09:33'	System	31 Aug 2020 16:35:35
	System	31 Aug 2020 16:35:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '31 Aug 2020 09:21'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '31 Aug 2020 11:51'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:14:18', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '115e6655-3d86-471b-ab56-596f9b132876' User entered 'None (1)'	System	31 Aug 2020 20:15:18
	System	31 Aug 2020 20:15:18

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:14:22', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '115e6655-3d86-471b-ab56-596f9b132876'	System	31 Aug 2020 20:15:18
User entered 'No (N)'	System	31 Aug 2020 20:15:18

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:14:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '115e6655-3d86-471b-ab56-596f9b132876'	System	31 Aug 2020 20:15:18
User entered 'No (N)'	System	31 Aug 2020 20:15:18

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:14:33', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '115e6655-3d86-471b-ab56-596f9b132876' User entered 'None (1)'	System	31 Aug 2020 20:15:18
	System	31 Aug 2020 20:15:18

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:14:42', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '115e6655-3d86-471b-ab56-596f9b132876'	System	31 Aug 2020 20:15:18
User entered '31 Aug 2020 13:14'	System	31 Aug 2020 20:15:18

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '31 Aug 2020 12:46'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 2'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:14', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '7d24d6d2-d5f1-442b-8fcf-c32b158ccb98' User entered 'None (1)'	System	01 Sep 2020 19:44:34
	System	01 Sep 2020 19:44:34

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:19', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '7d24d6d2-d5f1-442b-8fcf-c32b158ccb98'	System	01 Sep 2020 19:44:34
User entered 'No (N)'	System	01 Sep 2020 19:44:34

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:22', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '7d24d6d2-d5f1-442b-8fcf-c32b158ccb98'	System	01 Sep 2020 19:44:34
User entered 'No (N)'	System	01 Sep 2020 19:44:34

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '7d24d6d2-d5f1-442b-8fcf-c32b158ccb98' User entered 'None (1)'	System	01 Sep 2020 19:44:34
	System	01 Sep 2020 19:44:34

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:31', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '7d24d6d2-d5f1-442b-8fcf-c32b158ccb98'	System	01 Sep 2020 19:44:34
User entered '01 Sep 2020 12:44'	System	01 Sep 2020 19:44:34

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 3'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:19', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'c7c4cdd7-7f48-4334-9957-d7ee73b0cbf9'	System	02 Sep 2020 19:01:39
User entered 'None (1)'	System	02 Sep 2020 19:01:39

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:23', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'c7c4cdd7-7f48-4334-9957-d7ee73b0cbf9'	System	02 Sep 2020 19:01:39
User entered 'No (N)'	System	02 Sep 2020 19:01:39

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:26', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'c7c4cdd7-7f48-4334-9957-d7ee73b0cbf9'	System	02 Sep 2020 19:01:39
User entered 'No (N)'	System	02 Sep 2020 19:01:39

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:30', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'c7c4cdd7-7f48-4334-9957-d7ee73b0cbf9' User entered 'None (1)'	System	02 Sep 2020 19:01:39
	System	02 Sep 2020 19:01:39

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:34', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'c7c4cdd7-7f48-4334-9957-d7ee73b0cbf9'	System	02 Sep 2020 19:01:39
User entered '02 Sep 2020 12:01'	System	02 Sep 2020 19:01:39

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 4'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:13', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd17e0d0a-bc24-4e4f-a104-6a58bb2d56b0' User entered 'None (1)'	System	03 Sep 2020 20:47:35
	System	03 Sep 2020 20:47:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:18', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd17e0d0a-bc24-4e4f-a104-6a58bb2d56b0'	System	03 Sep 2020 20:47:35
User entered 'No (N)'	System	03 Sep 2020 20:47:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:22', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd17e0d0a-bc24-4e4f-a104-6a58bb2d56b0'	System	03 Sep 2020 20:47:35
User entered 'No (N)'	System	03 Sep 2020 20:47:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd17e0d0a-bc24-4e4f-a104-6a58bb2d56b0' User entered 'None (1)'	System	03 Sep 2020 20:47:35
	System	03 Sep 2020 20:47:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:32', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd17e0d0a-bc24-4e4f-a104-6a58bb2d56b0'	System	03 Sep 2020 20:47:35
User entered '03 Sep 2020 13:47'	System	03 Sep 2020 20:47:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 5'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:06', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b7635f3a-6dc5-46d4-a246-c0dee230a1df' User entered 'None (1)'	System	05 Sep 2020 15:30:23
	System	05 Sep 2020 15:30:23

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:11', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b7635f3a-6dc5-46d4-a246-c0dee230a1df' User entered 'No (N)'	System	05 Sep 2020 15:30:23
	System	05 Sep 2020 15:30:23

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:14', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b7635f3a-6dc5-46d4-a246-c0dee230a1df' User entered 'No (N)'	System	05 Sep 2020 15:30:23
	System	05 Sep 2020 15:30:23

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:18', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b7635f3a-6dc5-46d4-a246-c0dee230a1df' User entered 'None (1)'	System	05 Sep 2020 15:30:23
	System	05 Sep 2020 15:30:23

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:21', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b7635f3a-6dc5-46d4-a246-c0dee230a1df' User entered '05 Sep 2020 08:30'	System	05 Sep 2020 15:30:23
	System	05 Sep 2020 15:30:23

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 6'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:55:55', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b3f4351c-2ff0-441e-9735-80916c1adec0' User entered 'None (1)'	System	06 Sep 2020 15:56:10
	System	06 Sep 2020 15:56:10

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:55:58', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b3f4351c-2ff0-441e-9735-80916c1adec0' User entered 'No (N)'	System	06 Sep 2020 15:56:10
	System	06 Sep 2020 15:56:10

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:01', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b3f4351c-2ff0-441e-9735-80916c1adec0' User entered 'No (N)'	System	06 Sep 2020 15:56:10
	System	06 Sep 2020 15:56:10

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:05', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b3f4351c-2ff0-441e-9735-80916c1adec0' User entered 'None (1)'	System	06 Sep 2020 15:56:10
	System	06 Sep 2020 15:56:10

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:08', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b3f4351c-2ff0-441e-9735-80916c1adec0' User entered '06 Sep 2020 08:56'	System	06 Sep 2020 15:56:10
	System	06 Sep 2020 15:56:10

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 7'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:33:15', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '28a7f671-4474-4417-b01d-cc92564cbb93' User entered 'None (0)'	System	31 Aug 2020 16:35:48
	System	31 Aug 2020 16:35:48

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:33:20', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '28a7f671-4474-4417-b01d-cc92564cbb93'	System	31 Aug 2020 16:35:48
User entered 'None (0)'	System	31 Aug 2020 16:35:48

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:33:24', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '28a7f671-4474-4417-b01d-cc92564cbb93' User entered 'None (0)'	System	31 Aug 2020 16:35:48
	System	31 Aug 2020 16:35:48

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:33:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '28a7f671-4474-4417-b01d-cc92564cbb93' User entered 'None (0)'	System	31 Aug 2020 16:35:48
	System	31 Aug 2020 16:35:48

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:33:30', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '28a7f671-4474-4417-b01d-cc92564cbb93' User entered 'None (0)'	System	31 Aug 2020 16:35:48
	System	31 Aug 2020 16:35:48

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:33:36', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '28a7f671-4474-4417-b01d-cc92564cbb93'	System	31 Aug 2020 16:35:48
User entered 'None (0)'	System	31 Aug 2020 16:35:48

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:33:46', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '28a7f671-4474-4417-b01d-cc92564cbb93'	System	31 Aug 2020 16:35:48
User entered 'No (N)'	System	31 Aug 2020 16:35:48

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T09:33:52', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '28a7f671-4474-4417-b01d-cc92564cbb93' User entered '31 Aug 2020 09:33'	System	31 Aug 2020 16:35:48
	System	31 Aug 2020 16:35:48

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '31 Aug 2020 09:21'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '31 Aug 2020 11:51'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:14:50', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6b73dd16-0bcd-4be3-9f01-e43a0b4b2157'	System	31 Aug 2020 20:15:56
User entered 'None (0)'	System	31 Aug 2020 20:15:56

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:14:57', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6b73dd16-0bcd-4be3-9f01-e43a0b4b2157' User entered 'None (0)'	System	31 Aug 2020 20:15:56
	System	31 Aug 2020 20:15:56

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:15:01', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6b73dd16-0bcd-4be3-9f01-e43a0b4b2157'	System	31 Aug 2020 20:15:56
User entered 'None (0)'	System	31 Aug 2020 20:15:56

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:15:07', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6b73dd16-0bcd-4be3-9f01-e43a0b4b2157' User entered 'None (0)'	System	31 Aug 2020 20:15:56
	System	31 Aug 2020 20:15:56

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:15:10', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6b73dd16-0bcd-4be3-9f01-e43a0b4b2157'	System	31 Aug 2020 20:15:56
User entered 'None (0)'	System	31 Aug 2020 20:15:56

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:15:36', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6b73dd16-0bcd-4be3-9f01-e43a0b4b2157'	System	31 Aug 2020 20:15:56
User entered 'No interference with activity (1)'	System	31 Aug 2020 20:15:56

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:15:46', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6b73dd16-0bcd-4be3-9f01-e43a0b4b2157'	System	31 Aug 2020 20:15:56
User entered 'No (N)'	System	31 Aug 2020 20:15:56

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-08-31T13:15:52', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6b73dd16-0bcd-4be3-9f01-e43a0b4b2157'	System	31 Aug 2020 20:15:56
User entered '31 Aug 2020 13:15'	System	31 Aug 2020 20:15:56

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '31 Aug 2020 12:46'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 2'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:38', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6f52a040-d858-43e9-9931-902d3914ba98'	System	01 Sep 2020 19:45:11
User entered 'None (0)'	System	01 Sep 2020 19:45:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:40', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6f52a040-d858-43e9-9931-902d3914ba98'	System	01 Sep 2020 19:45:11
User entered 'None (0)'	System	01 Sep 2020 19:45:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:43', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6f52a040-d858-43e9-9931-902d3914ba98'	System	01 Sep 2020 19:45:11
User entered 'None (0)'	System	01 Sep 2020 19:45:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:46', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6f52a040-d858-43e9-9931-902d3914ba98' User entered 'None (0)'	System	01 Sep 2020 19:45:11
	System	01 Sep 2020 19:45:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:48', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6f52a040-d858-43e9-9931-902d3914ba98' User entered 'None (0)'	System	01 Sep 2020 19:45:11
	System	01 Sep 2020 19:45:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:44:50', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6f52a040-d858-43e9-9931-902d3914ba98'	System	01 Sep 2020 19:45:11
User entered 'None (0)'	System	01 Sep 2020 19:45:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:45:01', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6f52a040-d858-43e9-9931-902d3914ba98'	System	01 Sep 2020 19:45:11
User entered 'No (N)'	System	01 Sep 2020 19:45:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-01T12:45:07', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6f52a040-d858-43e9-9931-902d3914ba98'	System	01 Sep 2020 19:45:11
User entered '01 Sep 2020 12:45'	System	01 Sep 2020 19:45:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 3'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:47', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '746990ff-0c13-44be-b52d-8dcd93ce40bc' User entered 'None (0)'	System	02 Sep 2020 19:02:14
	System	02 Sep 2020 19:02:14

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:49', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '746990ff-0c13-44be-b52d-8dcd93ce40bc' User entered 'None (0)'	System	02 Sep 2020 19:02:14
	System	02 Sep 2020 19:02:14

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:52', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '746990ff-0c13-44be-b52d-8dcd93ce40bc' User entered 'None (0)'	System	02 Sep 2020 19:02:14
	System	02 Sep 2020 19:02:14

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:55', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '746990ff-0c13-44be-b52d-8dcd93ce40bc' User entered 'None (0)'	System	02 Sep 2020 19:02:14
	System	02 Sep 2020 19:02:14

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:01:59', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '746990ff-0c13-44be-b52d-8dcd93ce40bc' User entered 'None (0)'	System	02 Sep 2020 19:02:14
	System	02 Sep 2020 19:02:14

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:02:01', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '746990ff-0c13-44be-b52d-8dcd93ce40bc'	System	02 Sep 2020 19:02:14
User entered 'None (0)'	System	02 Sep 2020 19:02:14

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:02:07', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '746990ff-0c13-44be-b52d-8dcd93ce40bc'	System	02 Sep 2020 19:02:14
User entered 'No (N)'	System	02 Sep 2020 19:02:14

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-02T12:02:11', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '746990ff-0c13-44be-b52d-8dcd93ce40bc'	System	02 Sep 2020 19:02:14
User entered '02 Sep 2020 12:02'	System	02 Sep 2020 19:02:14

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 4'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:42', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9885479a-86d9-49f3-970e-a9a5a23f3977'	System	03 Sep 2020 20:48:11
User entered 'None (0)'	System	03 Sep 2020 20:48:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:46', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9885479a-86d9-49f3-970e-a9a5a23f3977'	System	03 Sep 2020 20:48:11
User entered 'None (0)'	System	03 Sep 2020 20:48:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:50', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9885479a-86d9-49f3-970e-a9a5a23f3977'	System	03 Sep 2020 20:48:11
User entered 'None (0)'	System	03 Sep 2020 20:48:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:53', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9885479a-86d9-49f3-970e-a9a5a23f3977'	System	03 Sep 2020 20:48:11
User entered 'None (0)'	System	03 Sep 2020 20:48:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:47:57', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9885479a-86d9-49f3-970e-a9a5a23f3977'	System	03 Sep 2020 20:48:11
User entered 'None (0)'	System	03 Sep 2020 20:48:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:48:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9885479a-86d9-49f3-970e-a9a5a23f3977'	System	03 Sep 2020 20:48:11
User entered 'None (0)'	System	03 Sep 2020 20:48:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:48:06', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9885479a-86d9-49f3-970e-a9a5a23f3977'	System	03 Sep 2020 20:48:11
User entered 'No (N)'	System	03 Sep 2020 20:48:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-03T13:48:09', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9885479a-86d9-49f3-970e-a9a5a23f3977'	System	03 Sep 2020 20:48:11
User entered '03 Sep 2020 13:48'	System	03 Sep 2020 20:48:11

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 5'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:26', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ef95171a-ac1f-49fb-a8d7-b84a35cb40db' User entered 'None (0)'	System	05 Sep 2020 15:30:51
	System	05 Sep 2020 15:30:51

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:29', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ef95171a-ac1f-49fb-a8d7-b84a35cb40db' User entered 'None (0)'	System	05 Sep 2020 15:30:51
	System	05 Sep 2020 15:30:51

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:31', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ef95171a-ac1f-49fb-a8d7-b84a35cb40db' User entered 'None (0)'	System	05 Sep 2020 15:30:51
	System	05 Sep 2020 15:30:51

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:34', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ef95171a-ac1f-49fb-a8d7-b84a35cb40db' User entered 'None (0)'	System	05 Sep 2020 15:30:51
	System	05 Sep 2020 15:30:51

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:36', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ef95171a-ac1f-49fb-a8d7-b84a35cb40db' User entered 'None (0)'	System	05 Sep 2020 15:30:51
	System	05 Sep 2020 15:30:51

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:39', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ef95171a-ac1f-49fb-a8d7-b84a35cb40db' User entered 'None (0)'	System	05 Sep 2020 15:30:51
	System	05 Sep 2020 15:30:51

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:44', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ef95171a-ac1f-49fb-a8d7-b84a35cb40db' User entered 'No (N)'	System	05 Sep 2020 15:30:51
	System	05 Sep 2020 15:30:51

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-05T08:30:47', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ef95171a-ac1f-49fb-a8d7-b84a35cb40db' User entered '05 Sep 2020 08:30'	System	05 Sep 2020 15:30:51
	System	05 Sep 2020 15:30:51

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 6'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:22', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'abe334e0-81d2-4360-aba0-98c3da44aa55' User entered 'None (0)'	System	06 Sep 2020 15:56:50
	System	06 Sep 2020 15:56:50

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'abe334e0-81d2-4360-aba0-98c3da44aa55'	System	06 Sep 2020 15:56:50
User entered 'None (0)'	System	06 Sep 2020 15:56:50

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:29', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'abe334e0-81d2-4360-aba0-98c3da44aa55' User entered 'None (0)'	System	06 Sep 2020 15:56:50
	System	06 Sep 2020 15:56:50

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:32', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'abe334e0-81d2-4360-aba0-98c3da44aa55' User entered 'None (0)'	System	06 Sep 2020 15:56:50
	System	06 Sep 2020 15:56:50

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:35', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'abe334e0-81d2-4360-aba0-98c3da44aa55'	System	06 Sep 2020 15:56:50
User entered 'None (0)'	System	06 Sep 2020 15:56:50

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:37', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'abe334e0-81d2-4360-aba0-98c3da44aa55' User entered 'None (0)'	System	06 Sep 2020 15:56:50
	System	06 Sep 2020 15:56:50

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:45', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'abe334e0-81d2-4360-aba0-98c3da44aa55'	System	06 Sep 2020 15:56:50
User entered 'No (N)'	System	06 Sep 2020 15:56:50

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-09-06T08:56:48', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'abe334e0-81d2-4360-aba0-98c3da44aa55'	System	06 Sep 2020 15:56:50
User entered '06 Sep 2020 08:56'	System	06 Sep 2020 15:56:50

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 7'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	06 Sep 2020 15:55:54
User entered 'Day 8'	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16

US3462388

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 15:55:54

US3462388

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 15:55:54

US3462388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:47:53
User entered 'Yes (Y)'		12 Oct 2020 16:06:17

US3462388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:47:53
User entered '08 Sep 2020'		12 Oct 2020 16:06:17

US3462388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:47:53
User entered 'Contact Made (CONTACT MADE)'		12 Oct 2020 16:06:17

US3462388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:47:53
User entered empty.		12 Oct 2020 16:06:17

US3462388

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:06:24

US3462388

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User entered 'I'	System	12 Oct 2020 16:06:24

US3462388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:03

US3462388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:03

US3462388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:03

US3462388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:03

US3462388

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:08

US3462388

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User entered 'I'	System	12 Oct 2020 16:07:08

US3462388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:44

US3462388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:44

US3462388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:44

US3462388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:44

US3462388

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:49

US3462388

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User entered 'I'	System	12 Oct 2020 16:07:49

US3462388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:23:29

US3462388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	12 Nov 2020 18:33:29
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'CONFIRMED' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 01:23:40
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	03 Nov 2020 01:23:29
User entered '12 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 01:23:29

US3462388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[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 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:23:29

US3462388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'VISIT2'	System	03 Nov 2020 01:23:29

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User accepted default value 'Pre-Dose (PREDOSE)'		03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '08:06'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '12 Oct 2020 08:06'	System	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '97.7' F	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Other (Other)'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'TYMPANIC'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '84'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'bpm'	System	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '14'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'breaths/min'	System	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '113'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'mmHg'	System	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '77'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'mmHg'	System	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User accepted default value 'Post-Dose (POSTDOSE)'		03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '09:28'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '12 Oct 2020 09:28'	System	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '97.7' F	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Other (Other)'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'TYMPANIC'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '84'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'bpm'	System	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '14'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'breaths/min'	System	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '112'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'mmHg'	System	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '80'	(b) (4), (b) (6)	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'mmHg'	System	03 Nov 2020 01:25:34

US3462388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:25:41

US3462388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:25:41

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is present in GCL but data not present in EDC, please clarify or reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 03:00:23
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is present in GCL but data not present in EDC, please clarify or reconcile' answered with 'DATE CONFIRMED' (Site from DM).		03 Nov 2020 01:25:55
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is present in GCL but data not present in EDC, please clarify or reconcile' (Site from DM).		30 Oct 2020 17:57:05
User entered 'Yes (Y)'		12 Oct 2020 16:11:38

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:11:38

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

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 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:11:38

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'MRNA-1273 OR PLACEBO'	System	12 Oct 2020 16:11:38

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:11:38

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '08:53'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:11:38

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '12 Oct 2020 08:53'	System	12 Oct 2020 16:11:38

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:11:38

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'ONCE'	System	12 Oct 2020 16:11:38

US3462388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'INTRAMUSCULAR'	System	12 Oct 2020 16:11:38

US3462388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 01:26:33

US3462388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '12 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 01:26:33

US3462388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '08:34'	(b) (4), (b) (6)	03 Nov 2020 01:26:33

US3462388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '12 Oct 2020 08:34'	System	03 Nov 2020 01:26:33

US3462388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:26:51

US3462388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		03 Nov 2020 01:26:51

US3462388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 01:26:51

US3462388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '08:29'	(b) (4), (b) (6)	03 Nov 2020 01:26:51

US3462388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '12 Oct 2020 08:29'	System	03 Nov 2020 01:26:51

US3462388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		03 Nov 2020 01:26:51

US3462388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 01:26:51

US3462388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:26:51

US3462388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered empty.	System	03 Nov 2020 01:26:51

US3462388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 01:26:56

US3462388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '1'	System	03 Nov 2020 01:26:56

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:25:50', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '67f4f586-4e10-4fe7-87c6-6dd2c713df07'	System	12 Oct 2020 16:26:08
User entered 'Yes (Y)'	System	12 Oct 2020 16:26:08

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:25:56', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '67f4f586-4e10-4fe7-87c6-6dd2c713df07'	System	12 Oct 2020 16:26:08
User entered '97.7'	System	12 Oct 2020 16:26:08

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '67f4f586-4e10-4fe7-87c6-6dd2c713df07'	System	12 Oct 2020 16:26:08
User entered 'No (N)'	System	12 Oct 2020 16:26:08

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:05', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '67f4f586-4e10-4fe7-87c6-6dd2c713df07'	System	12 Oct 2020 16:26:08
User entered '12 Oct 2020 09:26'	System	12 Oct 2020 16:26:08

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '12 Oct 2020 09:13'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '12 Oct 2020 11:43'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:22:54', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '933d2163-90d0-48a3-82b5-4feda9204509' User entered 'Yes (Y)'	System	13 Oct 2020 01:23:12
	System	13 Oct 2020 01:23:12

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:01', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '933d2163-90d0-48a3-82b5-4feda9204509' User entered '98.2'	System	13 Oct 2020 01:23:12
	System	13 Oct 2020 01:23:12

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:04', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '933d2163-90d0-48a3-82b5-4feda9204509'	System	13 Oct 2020 01:23:12
User entered 'No (N)'	System	13 Oct 2020 01:23:12

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:07', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '933d2163-90d0-48a3-82b5-4feda9204509'	System	13 Oct 2020 01:23:12
User entered '12 Oct 2020 18:23'	System	13 Oct 2020 01:23:12

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '12 Oct 2020 12:38'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 2'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:13', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ccb2a045-5dfb-40f7-ae94-6f900aa47f9a' User entered 'Yes (Y)'	System	14 Oct 2020 09:43:29
	System	14 Oct 2020 09:43:29

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:21', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ccb2a045-5dfb-40f7-ae94-6f900aa47f9a' User entered '97.9'	System	14 Oct 2020 09:43:29
	System	14 Oct 2020 09:43:29

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:25', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ccb2a045-5dfb-40f7-ae94-6f900aa47f9a'	System	14 Oct 2020 09:43:29
User entered 'No (N)'	System	14 Oct 2020 09:43:29

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ccb2a045-5dfb-40f7-ae94-6f900aa47f9a' User entered '14 Oct 2020 02:43'	System	14 Oct 2020 09:43:29
	System	14 Oct 2020 09:43:29

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 3'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:17:29', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1befcd5a-b48e-4936-a8ef-ce9a02de4e6a' User entered 'Yes (Y)'	System	15 Oct 2020 09:17:43
	System	15 Oct 2020 09:17:43

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:17:35', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1befcd5a-b48e-4936-a8ef-ce9a02de4e6a' User entered '98.2'	System	15 Oct 2020 09:17:43
	System	15 Oct 2020 09:17:43

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:17:38', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1befcd5a-b48e-4936-a8ef-ce9a02de4e6a'	System	15 Oct 2020 09:17:43
User entered 'No (N)'	System	15 Oct 2020 09:17:43

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:17:40', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1befcd5a-b48e-4936-a8ef-ce9a02de4e6a'	System	15 Oct 2020 09:17:43
User entered '15 Oct 2020 02:17'	System	15 Oct 2020 09:17:43

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 4'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:11', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '549c27a0-a9b7-4e04-bf2a-9711ed41a278' User entered 'Yes (Y)'	System	15 Oct 2020 22:35:24
	System	15 Oct 2020 22:35:24

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:16', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '549c27a0-a9b7-4e04-bf2a-9711ed41a278' User entered '98.2'	System	15 Oct 2020 22:35:24
	System	15 Oct 2020 22:35:24

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:19', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '549c27a0-a9b7-4e04-bf2a-9711ed41a278'	System	15 Oct 2020 22:35:24
User entered 'No (N)'	System	15 Oct 2020 22:35:24

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:21', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '549c27a0-a9b7-4e04-bf2a-9711ed41a278' User entered '15 Oct 2020 15:35'	System	15 Oct 2020 22:35:24
	System	15 Oct 2020 22:35:24

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 5'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:22:35', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '082adfc4-8fb4-4ca5-8c72-c550032d5e02'	System	17 Oct 2020 12:22:48
User entered 'Yes (Y)'	System	17 Oct 2020 12:22:48

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:22:40', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '082adfc4-8fb4-4ca5-8c72-c550032d5e02'	System	17 Oct 2020 12:22:48
User entered '98.2'	System	17 Oct 2020 12:22:48

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:22:44', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '082adfc4-8fb4-4ca5-8c72-c550032d5e02'	System	17 Oct 2020 12:22:48
User entered 'No (N)'	System	17 Oct 2020 12:22:48

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:22:46', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '082adfc4-8fb4-4ca5-8c72-c550032d5e02'	System	17 Oct 2020 12:22:48
User entered '17 Oct 2020 05:22'	System	17 Oct 2020 12:22:48

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 6'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:39:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b39cb899-8a30-448f-a77f-9d3be1054983'	System	18 Oct 2020 14:39:45
User entered 'Yes (Y)'	System	18 Oct 2020 14:39:45

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:39:34', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b39cb899-8a30-448f-a77f-9d3be1054983'	System	18 Oct 2020 14:39:45
User entered '97.8'	System	18 Oct 2020 14:39:45

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:39:38', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b39cb899-8a30-448f-a77f-9d3be1054983'	System	18 Oct 2020 14:39:45
User entered 'No (N)'	System	18 Oct 2020 14:39:45

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:39:41', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'b39cb899-8a30-448f-a77f-9d3be1054983'	System	18 Oct 2020 14:39:45
User entered '18 Oct 2020 07:39'	System	18 Oct 2020 14:39:45

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 7'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:17', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1afb8605-f6d0-4834-aa69-1a40b10284a7' User entered 'Yes (Y)'	System	19 Oct 2020 09:54:31
	System	19 Oct 2020 09:54:31

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:23', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1afb8605-f6d0-4834-aa69-1a40b10284a7' User entered '98.2'	System	19 Oct 2020 09:54:31
	System	19 Oct 2020 09:54:31

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:26', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1afb8605-f6d0-4834-aa69-1a40b10284a7'	System	19 Oct 2020 09:54:31
User entered 'No (N)'	System	19 Oct 2020 09:54:31

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:29', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1afb8605-f6d0-4834-aa69-1a40b10284a7' User entered '19 Oct 2020 02:54'	System	19 Oct 2020 09:54:31
	System	19 Oct 2020 09:54:31

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:14', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9b9de567-a672-490e-86bf-96b20d10f08a' User entered 'None (1)'	System	12 Oct 2020 16:26:36
	System	12 Oct 2020 16:26:36

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:18', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9b9de567-a672-490e-86bf-96b20d10f08a' User entered 'No (N)'	System	12 Oct 2020 16:26:36
	System	12 Oct 2020 16:26:36

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:21', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9b9de567-a672-490e-86bf-96b20d10f08a' User entered 'No (N)'	System	12 Oct 2020 16:26:36
	System	12 Oct 2020 16:26:36

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9b9de567-a672-490e-86bf-96b20d10f08a' User entered 'None (1)'	System	12 Oct 2020 16:26:36
	System	12 Oct 2020 16:26:36

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:31', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '9b9de567-a672-490e-86bf-96b20d10f08a' User entered '12 Oct 2020 09:26'	System	12 Oct 2020 16:26:36
	System	12 Oct 2020 16:26:36

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '12 Oct 2020 09:13'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '12 Oct 2020 11:43'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:11', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd392cc3f-b9d7-4b02-af82-dde693a81aea' User entered 'None (1)'	System	13 Oct 2020 01:23:29
	System	13 Oct 2020 01:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:15', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd392cc3f-b9d7-4b02-af82-dde693a81aea'	System	13 Oct 2020 01:23:29
User entered 'No (N)'	System	13 Oct 2020 01:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:18', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd392cc3f-b9d7-4b02-af82-dde693a81aea' User entered 'No (N)'	System	13 Oct 2020 01:23:29
	System	13 Oct 2020 01:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:22', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd392cc3f-b9d7-4b02-af82-dde693a81aea' User entered 'None (1)'	System	13 Oct 2020 01:23:29
	System	13 Oct 2020 01:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd392cc3f-b9d7-4b02-af82-dde693a81aea'	System	13 Oct 2020 01:23:29
User entered '12 Oct 2020 18:23'	System	13 Oct 2020 01:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '12 Oct 2020 12:38'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 2'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:31', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '43ccac99-be71-4c6a-b3e6-208929af48d9' User entered 'None (1)'	System	14 Oct 2020 09:43:45
	System	14 Oct 2020 09:43:45

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:34', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '43ccac99-be71-4c6a-b3e6-208929af48d9'	System	14 Oct 2020 09:43:45
User entered 'No (N)'	System	14 Oct 2020 09:43:45

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:36', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '43ccac99-be71-4c6a-b3e6-208929af48d9'	System	14 Oct 2020 09:43:45
User entered 'No (N)'	System	14 Oct 2020 09:43:45

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:39', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '43ccac99-be71-4c6a-b3e6-208929af48d9' User entered 'None (1)'	System	14 Oct 2020 09:43:45
	System	14 Oct 2020 09:43:45

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:41', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '43ccac99-be71-4c6a-b3e6-208929af48d9' User entered '14 Oct 2020 02:43'	System	14 Oct 2020 09:43:45
	System	14 Oct 2020 09:43:45

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 3'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:17:44', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'a5ed34cc-455f-45fd-a9f6-d77eb59ebb32'	System	15 Oct 2020 09:17:56
User entered 'None (1)'	System	15 Oct 2020 09:17:56

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:17:47', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'a5ed34cc-455f-45fd-a9f6-d77eb59ebb32'	System	15 Oct 2020 09:17:56
User entered 'No (N)'	System	15 Oct 2020 09:17:56

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:17:50', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'a5ed34cc-455f-45fd-a9f6-d77eb59ebb32'	System	15 Oct 2020 09:17:56
User entered 'No (N)'	System	15 Oct 2020 09:17:56

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:17:52', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'a5ed34cc-455f-45fd-a9f6-d77eb59ebb32'	System	15 Oct 2020 09:17:56
User entered 'None (1)'	System	15 Oct 2020 09:17:56

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:17:54', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'a5ed34cc-455f-45fd-a9f6-d77eb59ebb32'	System	15 Oct 2020 09:17:56
User entered '15 Oct 2020 02:17'	System	15 Oct 2020 09:17:56

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 4'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:24', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd78546aa-8c91-448d-b79d-aa5e79faa451' User entered 'None (1)'	System	15 Oct 2020 22:35:37
	System	15 Oct 2020 22:35:37

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:27', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd78546aa-8c91-448d-b79d-aa5e79faa451'	System	15 Oct 2020 22:35:37
User entered 'No (N)'	System	15 Oct 2020 22:35:37

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:30', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd78546aa-8c91-448d-b79d-aa5e79faa451'	System	15 Oct 2020 22:35:37
User entered 'No (N)'	System	15 Oct 2020 22:35:37

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:31', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd78546aa-8c91-448d-b79d-aa5e79faa451' User entered 'None (1)'	System	15 Oct 2020 22:35:37
	System	15 Oct 2020 22:35:37

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:33', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'd78546aa-8c91-448d-b79d-aa5e79faa451' User entered '15 Oct 2020 15:35'	System	15 Oct 2020 22:35:37
	System	15 Oct 2020 22:35:37

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 5'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:22:51', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '06c56e0f-a073-41ca-a88a-01fc02548222'	System	17 Oct 2020 12:23:06
User entered 'None (1)'	System	17 Oct 2020 12:23:06

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:22:54', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '06c56e0f-a073-41ca-a88a-01fc02548222'	System	17 Oct 2020 12:23:06
User entered 'No (N)'	System	17 Oct 2020 12:23:06

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:22:56', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '06c56e0f-a073-41ca-a88a-01fc02548222'	System	17 Oct 2020 12:23:06
User entered 'No (N)'	System	17 Oct 2020 12:23:06

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:22:59', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '06c56e0f-a073-41ca-a88a-01fc02548222'	System	17 Oct 2020 12:23:06
User entered 'None (1)'	System	17 Oct 2020 12:23:06

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:23:01', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '06c56e0f-a073-41ca-a88a-01fc02548222'	System	17 Oct 2020 12:23:06
User entered '17 Oct 2020 05:23'	System	17 Oct 2020 12:23:06

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 6'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:39:45', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '58a8dc59-78a8-4e88-acce-9399708e68d9' User entered 'None (1)'	System	18 Oct 2020 14:40:01
	System	18 Oct 2020 14:40:01

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:39:48', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '58a8dc59-78a8-4e88-acce-9399708e68d9'	System	18 Oct 2020 14:40:01
User entered 'No (N)'	System	18 Oct 2020 14:40:01

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:39:51', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '58a8dc59-78a8-4e88-acce-9399708e68d9' User entered 'No (N)'	System	18 Oct 2020 14:40:01
	System	18 Oct 2020 14:40:01

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:39:56', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '58a8dc59-78a8-4e88-acce-9399708e68d9' User entered 'None (1)'	System	18 Oct 2020 14:40:01
	System	18 Oct 2020 14:40:01

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:39:59', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '58a8dc59-78a8-4e88-acce-9399708e68d9'	System	18 Oct 2020 14:40:01
User entered '18 Oct 2020 07:39'	System	18 Oct 2020 14:40:01

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 7'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:33', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '66578a24-d331-4464-8cd5-a43403cf4de7' User entered 'None (1)'	System	19 Oct 2020 09:54:48
	System	19 Oct 2020 09:54:48

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:36', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '66578a24-d331-4464-8cd5-a43403cf4de7'	System	19 Oct 2020 09:54:48
User entered 'No (N)'	System	19 Oct 2020 09:54:48

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:39', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '66578a24-d331-4464-8cd5-a43403cf4de7'	System	19 Oct 2020 09:54:48
User entered 'No (N)'	System	19 Oct 2020 09:54:48

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:43', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '66578a24-d331-4464-8cd5-a43403cf4de7' User entered 'None (1)'	System	19 Oct 2020 09:54:48
	System	19 Oct 2020 09:54:48

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:45', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '66578a24-d331-4464-8cd5-a43403cf4de7'	System	19 Oct 2020 09:54:48
User entered '19 Oct 2020 02:54'	System	19 Oct 2020 09:54:48

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:36', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '3110d1f1-4d29-4921-809a-5dc709898d2a' User entered 'None (0)'	System	12 Oct 2020 16:27:00
	System	12 Oct 2020 16:27:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:39', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '3110d1f1-4d29-4921-809a-5dc709898d2a' User entered 'None (0)'	System	12 Oct 2020 16:27:00
	System	12 Oct 2020 16:27:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:43', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '3110d1f1-4d29-4921-809a-5dc709898d2a' User entered 'None (0)'	System	12 Oct 2020 16:27:00
	System	12 Oct 2020 16:27:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:45', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '3110d1f1-4d29-4921-809a-5dc709898d2a' User entered 'None (0)'	System	12 Oct 2020 16:27:00
	System	12 Oct 2020 16:27:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:48', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '3110d1f1-4d29-4921-809a-5dc709898d2a' User entered 'None (0)'	System	12 Oct 2020 16:27:00
	System	12 Oct 2020 16:27:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:50', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '3110d1f1-4d29-4921-809a-5dc709898d2a' User entered 'None (0)'	System	12 Oct 2020 16:27:00
	System	12 Oct 2020 16:27:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:54', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '3110d1f1-4d29-4921-809a-5dc709898d2a'	System	12 Oct 2020 16:27:00
User entered 'No (N)'	System	12 Oct 2020 16:27:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T09:26:57', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '3110d1f1-4d29-4921-809a-5dc709898d2a'	System	12 Oct 2020 16:27:00
User entered '12 Oct 2020 09:26'	System	12 Oct 2020 16:27:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '12 Oct 2020 09:13'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '12 Oct 2020 11:43'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:31', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1e320c38-effc-40c2-be81-a906d0c8a73a' User entered 'None (0)'	System	13 Oct 2020 01:23:56
	System	13 Oct 2020 01:23:56

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:33', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1e320c38-effc-40c2-be81-a906d0c8a73a' User entered 'None (0)'	System	13 Oct 2020 01:23:56
	System	13 Oct 2020 01:23:56

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:36', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1e320c38-effc-40c2-be81-a906d0c8a73a' User entered 'None (0)'	System	13 Oct 2020 01:23:56
	System	13 Oct 2020 01:23:56

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:40', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1e320c38-effc-40c2-be81-a906d0c8a73a' User entered 'None (0)'	System	13 Oct 2020 01:23:56
	System	13 Oct 2020 01:23:56

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:43', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1e320c38-effc-40c2-be81-a906d0c8a73a' User entered 'None (0)'	System	13 Oct 2020 01:23:56
	System	13 Oct 2020 01:23:56

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:45', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1e320c38-effc-40c2-be81-a906d0c8a73a' User entered 'None (0)'	System	13 Oct 2020 01:23:56
	System	13 Oct 2020 01:23:56

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:52', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1e320c38-effc-40c2-be81-a906d0c8a73a'	System	13 Oct 2020 01:23:56
User entered 'No (N)'	System	13 Oct 2020 01:23:56

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-12T18:23:55', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1e320c38-effc-40c2-be81-a906d0c8a73a' User entered '12 Oct 2020 18:23'	System	13 Oct 2020 01:23:56
	System	13 Oct 2020 01:23:56

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '12 Oct 2020 12:38'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 2'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:45', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'e7f777c9-d927-488c-9eaf-a3dcd94fb5f3'	System	14 Oct 2020 09:44:08
User entered 'None (0)'	System	14 Oct 2020 09:44:08

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:47', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'e7f777c9-d927-488c-9eaf-a3dcd94fb5f3'	System	14 Oct 2020 09:44:08
User entered 'None (0)'	System	14 Oct 2020 09:44:08

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:50', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'e7f777c9-d927-488c-9eaf-a3dcd94fb5f3' User entered 'None (0)'	System	14 Oct 2020 09:44:08
	System	14 Oct 2020 09:44:08

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:53', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'e7f777c9-d927-488c-9eaf-a3dcd94fb5f3' User entered 'None (0)'	System	14 Oct 2020 09:44:08
	System	14 Oct 2020 09:44:08

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:55', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'e7f777c9-d927-488c-9eaf-a3dcd94fb5f3'	System	14 Oct 2020 09:44:08
User entered 'None (0)'	System	14 Oct 2020 09:44:08

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:43:57', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'e7f777c9-d927-488c-9eaf-a3dcd94fb5f3' User entered 'None (0)'	System	14 Oct 2020 09:44:08
	System	14 Oct 2020 09:44:08

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:44:03', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'e7f777c9-d927-488c-9eaf-a3dcd94fb5f3'	System	14 Oct 2020 09:44:08
User entered 'No (N)'	System	14 Oct 2020 09:44:08

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-14T02:44:06', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'e7f777c9-d927-488c-9eaf-a3dcd94fb5f3' User entered '14 Oct 2020 02:44'	System	14 Oct 2020 09:44:08
	System	14 Oct 2020 09:44:08

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 3'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:17:58', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'bfe4a9e9-159d-499c-b793-8b9f7d79789a' User entered 'None (0)'	System	15 Oct 2020 09:18:16
	System	15 Oct 2020 09:18:16

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:18:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'bfe4a9e9-159d-499c-b793-8b9f7d79789a' User entered 'None (0)'	System	15 Oct 2020 09:18:16
	System	15 Oct 2020 09:18:16

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:18:02', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'bfe4a9e9-159d-499c-b793-8b9f7d79789a' User entered 'None (0)'	System	15 Oct 2020 09:18:16
	System	15 Oct 2020 09:18:16

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:18:04', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'bfe4a9e9-159d-499c-b793-8b9f7d79789a' User entered 'None (0)'	System	15 Oct 2020 09:18:16
	System	15 Oct 2020 09:18:16

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:18:06', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'bfe4a9e9-159d-499c-b793-8b9f7d79789a' User entered 'None (0)'	System	15 Oct 2020 09:18:16
	System	15 Oct 2020 09:18:16

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:18:09', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'bfe4a9e9-159d-499c-b793-8b9f7d79789a' User entered 'None (0)'	System	15 Oct 2020 09:18:16
	System	15 Oct 2020 09:18:16

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:18:13', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'bfe4a9e9-159d-499c-b793-8b9f7d79789a'	System	15 Oct 2020 09:18:16
User entered 'No (N)'	System	15 Oct 2020 09:18:16

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T02:18:15', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'bfe4a9e9-159d-499c-b793-8b9f7d79789a' User entered '15 Oct 2020 02:18'	System	15 Oct 2020 09:18:16
	System	15 Oct 2020 09:18:16

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 4'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:37', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ac50a432-4bf6-47b8-8630-4ee50030c6c1' User entered 'None (0)'	System	15 Oct 2020 22:36:00
	System	15 Oct 2020 22:36:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:39', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ac50a432-4bf6-47b8-8630-4ee50030c6c1' User entered 'None (0)'	System	15 Oct 2020 22:36:00
	System	15 Oct 2020 22:36:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:41', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ac50a432-4bf6-47b8-8630-4ee50030c6c1' User entered 'None (0)'	System	15 Oct 2020 22:36:00
	System	15 Oct 2020 22:36:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:45', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ac50a432-4bf6-47b8-8630-4ee50030c6c1' User entered 'None (0)'	System	15 Oct 2020 22:36:00
	System	15 Oct 2020 22:36:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:47', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ac50a432-4bf6-47b8-8630-4ee50030c6c1' User entered 'None (0)'	System	15 Oct 2020 22:36:00
	System	15 Oct 2020 22:36:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:49', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ac50a432-4bf6-47b8-8630-4ee50030c6c1' User entered 'None (0)'	System	15 Oct 2020 22:36:00
	System	15 Oct 2020 22:36:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:54', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ac50a432-4bf6-47b8-8630-4ee50030c6c1' User entered 'No (N)'	System	15 Oct 2020 22:36:00
	System	15 Oct 2020 22:36:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-15T15:35:56', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'ac50a432-4bf6-47b8-8630-4ee50030c6c1' User entered '15 Oct 2020 15:35'	System	15 Oct 2020 22:36:00
	System	15 Oct 2020 22:36:00

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 5'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:23:05', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1a2ceeee-0d9b-4044-a981-e60f598a65c1' User entered 'None (0)'	System	17 Oct 2020 12:23:29
	System	17 Oct 2020 12:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:23:07', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1a2ceeee-0d9b-4044-a981-e60f598a65c1' User entered 'None (0)'	System	17 Oct 2020 12:23:29
	System	17 Oct 2020 12:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:23:10', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1a2ceeee-0d9b-4044-a981-e60f598a65c1' User entered 'None (0)'	System	17 Oct 2020 12:23:29
	System	17 Oct 2020 12:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:23:14', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1a2ceeee-0d9b-4044-a981-e60f598a65c1' User entered 'None (0)'	System	17 Oct 2020 12:23:29
	System	17 Oct 2020 12:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:23:17', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1a2ceeee-0d9b-4044-a981-e60f598a65c1' User entered 'None (0)'	System	17 Oct 2020 12:23:29
	System	17 Oct 2020 12:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:23:19', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1a2ceeee-0d9b-4044-a981-e60f598a65c1' User entered 'None (0)'	System	17 Oct 2020 12:23:29
	System	17 Oct 2020 12:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:23:22', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1a2ceeee-0d9b-4044-a981-e60f598a65c1' User entered 'No (N)'	System	17 Oct 2020 12:23:29
	System	17 Oct 2020 12:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-17T05:23:25', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '1a2ceeee-0d9b-4044-a981-e60f598a65c1' User entered '17 Oct 2020 05:23'	System	17 Oct 2020 12:23:29
	System	17 Oct 2020 12:23:29

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 6'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:40:03', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '25429334-0070-4545-a928-318fc528b083' User entered 'None (0)'	System	18 Oct 2020 14:40:27
	System	18 Oct 2020 14:40:27

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:40:05', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '25429334-0070-4545-a928-318fc528b083' User entered 'None (0)'	System	18 Oct 2020 14:40:27
	System	18 Oct 2020 14:40:27

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:40:09', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '25429334-0070-4545-a928-318fc528b083' User entered 'None (0)'	System	18 Oct 2020 14:40:27
	System	18 Oct 2020 14:40:27

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:40:13', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '25429334-0070-4545-a928-318fc528b083' User entered 'None (0)'	System	18 Oct 2020 14:40:27
	System	18 Oct 2020 14:40:27

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:40:15', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '25429334-0070-4545-a928-318fc528b083' User entered 'None (0)'	System	18 Oct 2020 14:40:27
	System	18 Oct 2020 14:40:27

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:40:18', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '25429334-0070-4545-a928-318fc528b083' User entered 'None (0)'	System	18 Oct 2020 14:40:27
	System	18 Oct 2020 14:40:27

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:40:23', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '25429334-0070-4545-a928-318fc528b083'	System	18 Oct 2020 14:40:27
User entered 'No (N)'	System	18 Oct 2020 14:40:27

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-18T07:40:25', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '25429334-0070-4545-a928-318fc528b083'	System	18 Oct 2020 14:40:27
User entered '18 Oct 2020 07:40'	System	18 Oct 2020 14:40:27

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	12 Oct 2020 16:11:38
User entered 'Day 7'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:49', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'dbdf8ca0-3933-4787-9459-5644cfe0bb83'	System	19 Oct 2020 09:55:11
User entered 'None (0)'	System	19 Oct 2020 09:55:11

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:51', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'dbdf8ca0-3933-4787-9459-5644cfe0bb83'	System	19 Oct 2020 09:55:11
User entered 'None (0)'	System	19 Oct 2020 09:55:11

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:54', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'dbdf8ca0-3933-4787-9459-5644cfe0bb83' User entered 'None (0)'	System	19 Oct 2020 09:55:11
	System	19 Oct 2020 09:55:11

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:56', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'dbdf8ca0-3933-4787-9459-5644cfe0bb83' User entered 'None (0)'	System	19 Oct 2020 09:55:11
	System	19 Oct 2020 09:55:11

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:54:58', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'dbdf8ca0-3933-4787-9459-5644cfe0bb83'	System	19 Oct 2020 09:55:11
User entered 'None (0)'	System	19 Oct 2020 09:55:11

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:55:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'dbdf8ca0-3933-4787-9459-5644cfe0bb83'	System	19 Oct 2020 09:55:11
User entered 'None (0)'	System	19 Oct 2020 09:55:11

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:55:06', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'dbdf8ca0-3933-4787-9459-5644cfe0bb83'	System	19 Oct 2020 09:55:11
User entered 'No (N)'	System	19 Oct 2020 09:55:11

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-10-19T02:55:08', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'dbdf8ca0-3933-4787-9459-5644cfe0bb83'	System	19 Oct 2020 09:55:11
User entered '19 Oct 2020 02:55'	System	19 Oct 2020 09:55:11

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 16:11:38

US3462388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 16:11:38

US3462388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 01:27:38

US3462388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '19 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 01:27:38

US3462388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:27:38

US3462388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:27:38

US3462388

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 01:27:45

US3462388

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User entered 'I'	System	03 Nov 2020 01:27:45

US3462388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 01:30:06

US3462388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '26 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 01:30:06

US3462388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:30:06

US3462388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:30:06

US3462388

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:30:11

US3462388

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User entered 'I'	System	03 Nov 2020 01:30:11

US3462388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 01:30:36

US3462388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:33:42
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'DATE CONFIRMED' (Site from System).		03 Nov 2020 01:30:57
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Nov 2020 01:30:36
User entered '30 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 01:30:36

US3462388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:30:36

US3462388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:30:36

US3462388

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:31:04

US3462388

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:00
User entered 'I'	System	03 Nov 2020 01:31:04

US3462388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 01:31:25

US3462388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:33:55
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'DATE CONFIRMED' (Site from System).		03 Nov 2020 01:31:37
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	03 Nov 2020 01:31:25
User entered '02 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 01:31:25

US3462388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[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 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:31:25

US3462388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'VISIT3'	System	03 Nov 2020 01:31:25

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered empty.	System	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered empty.	System	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered empty.	System	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered empty.	System	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered empty.	System	03 Nov 2020 01:31:53

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30

US3462388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30

US3462388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 01:31:58

US3462388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:52
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 01:31:58

US3462388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 01:32:18

US3462388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '02 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 01:32:18

US3462388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered '08:00'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:32:18

US3462388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered '02 Nov 2020 08:00'	System	03 Nov 2020 01:32:18

US3462388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:01:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 01:32:24

US3462388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'I'	System	03 Nov 2020 01:32:24

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 64'	System	31 Aug 2020 16:15:35

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-11-03T17:44:38', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6c710e24-be02-44f4-ba4e-a47af8de62c6'	System	04 Nov 2020 01:44:51
User entered 'No (N)'	System	04 Nov 2020 01:44:51

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Have you been exposed to someone with 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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-11-03T17:44:43', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6c710e24-be02-44f4-ba4e-a47af8de62c6'	System	04 Nov 2020 01:44:51
User entered 'No (N)'	System	04 Nov 2020 01:44:51

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-11-03T17:44:47', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '6c710e24-be02-44f4-ba4e-a47af8de62c6' User entered '03 Nov 2020 17:44:47'	System	04 Nov 2020 01:44:51
	System	04 Nov 2020 01:44:51

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 16:15:35

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 71'	System	31 Aug 2020 16:15:35

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-11-07T06:45:49', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '534413eb-afaa-4df6-8564-fbaf6e437c81' User entered 'No (N)'	System	07 Nov 2020 14:46:05
	System	07 Nov 2020 14:46:05

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Have you been exposed to someone with 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 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-11-07T06:45:55', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '534413eb-afaa-4df6-8564-fbaf6e437c81'	System	07 Nov 2020 14:46:05
User entered 'No (N)'	System	07 Nov 2020 14:46:05

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CFAE4EA-64D4-490B-B1F2-3D8824772F14)', Time: '2020-11-07T06:46:02', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '534413eb-afaa-4df6-8564-fbaf6e437c81' User entered '07 Nov 2020 06:46:02'	System	07 Nov 2020 14:46:05
	System	07 Nov 2020 14:46:05

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 16:15:35

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:46:16
Data entry locked.	System	31 Aug 2020 16:15:35
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04
Data entry locked.	System	31 Aug 2020 16:15:35
User entered 'Day 78'	System	31 Aug 2020 16:15:35

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04
Data entry locked.	System	31 Aug 2020 16:15:35
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 16:15:35

US3462388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:53:04
Data entry locked.	System	31 Aug 2020 16:15:35
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 16:15:35

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:53:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[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 (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-08T13:11:26-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '5e68c03c-f9f9-446e-8a63-27eeef1dd907'	System	08 Apr 2021 20:11:44
User entered 'No (N)'	System	08 Apr 2021 20:11:44

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Have you been exposed to someone with 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 (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-08T13:11:30-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '5e68c03c-f9f9-446e-8a63-27eeef1dd907'	System	08 Apr 2021 20:11:44
User entered 'No (N)'	System	08 Apr 2021 20:11:44

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-08T13:11:40-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '5e68c03c-f9f9-446e-8a63-27eeef1dd907'	System	08 Apr 2021 20:11:44
User entered '08 Apr 2021 13:11:40'	System	08 Apr 2021 20:11:44

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[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 (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-14T20:44:26-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '0568fecb-7e5f-4d04-8c44-71110a88bf26'	System	15 Apr 2021 03:44:42
User entered 'No (N)'	System	15 Apr 2021 03:44:42

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Have you been exposed to someone with 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 (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-14T20:44:32-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '0568fecb-7e5f-4d04-8c44-71110a88bf26'	System	15 Apr 2021 03:44:42
User entered 'No (N)'	System	15 Apr 2021 03:44:42

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-14T20:44:36-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '0568fecb-7e5f-4d04-8c44-71110a88bf26'	System	15 Apr 2021 03:44:42
User entered '14 Apr 2021 20:44:36'	System	15 Apr 2021 03:44:42

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[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 (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-21T16:23:08-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '523a943a-1eb3-4681-96a3-55e97e120200'	System	21 Apr 2021 23:23:19
User entered 'No (N)'	System	21 Apr 2021 23:23:19

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Have you been exposed to someone with 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 (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-21T16:23:13-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '523a943a-1eb3-4681-96a3-55e97e120200'	System	21 Apr 2021 23:23:19
User entered 'No (N)'	System	21 Apr 2021 23:23:19

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-21T16:23:16-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '523a943a-1eb3-4681-96a3-55e97e120200'	System	21 Apr 2021 23:23:19
User entered '21 Apr 2021 16:23:16'	System	21 Apr 2021 23:23:19

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[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 (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-30T12:13:00-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'f509a71a-6673-4f7d-b969-111e76703d13' User entered 'No (N)'	System	30 Apr 2021 19:13:25
	System	30 Apr 2021 19:13:25

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

Have you been exposed to someone with 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 (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-30T12:13:03-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'f509a71a-6673-4f7d-b969-111e76703d13' User entered 'No (N)'	System	30 Apr 2021 19:13:25
	System	30 Apr 2021 19:13:25

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-30T12:13:19-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: 'f509a71a-6673-4f7d-b969-111e76703d13' User entered '30 Apr 2021 12:13:19'	System	30 Apr 2021 19:13:25
	System	30 Apr 2021 19:13:25

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 20:53:04

US3462388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:53:04
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 20:53:04

US3462388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-08T13:11:52-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '0b1125a6-f003-4964-af9f-cffbf6f51af7'	System	08 Apr 2021 20:12:04
User entered 'No (N)'	System	08 Apr 2021 20:12:04

US3462388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:47:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6255D75C-7B22-4967-823D-87D95103A12F)', Time: '2021-04-08T13:11:58-07:00', User OID: 'PatientReportedOutcome (US3462388)', ODM File OID: '0b1125a6-f003-4964-af9f-cffbf6f51af7' User entered '08 Apr 2021 13:11:58'	System	08 Apr 2021 20:12:04
	System	08 Apr 2021 20:12:04

US3462388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 01:57:04
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 03-Mar-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision OL-D1 Visit. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).		30 Mar 2021 01:55:31
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 03-Mar-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision OL-D1 Visit. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		26 Mar 2021 07:45:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:08:01

US3462388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 01:57:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 06:09:36
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'		17 Dec 2020 17:08:26
answered with 'date is correct' (Site from System).		
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Dec 2020 17:08:01
User entered '30 Nov 2020'	(b) (4), (b) (6)	17 Dec 2020 17:08:01

US3462388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 01:57:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:08:01

US3462388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 01:57:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 17:08:01

US3462388

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:08:07

US3462388

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:53:30
User entered 'I'	System	17 Dec 2020 17:08:07

US3462388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:45:14

US3462388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:45:14

US3462388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:45:14

US3462388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 16:45:14

US3462388

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:45:21

US3462388

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User entered 'I'	System	05 Apr 2021 16:45:21

US3462388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:15

US3462388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered '8 Feb 2021'	(b) (4), (b) (6)	05 Apr 2021 16:46:15

US3462388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:15

US3462388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered 'patient called but not contacted, message left'	(b) (4), (b) (6)	05 Apr 2021 16:46:15

US3462388

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:19

US3462388

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User entered 'I'	System	05 Apr 2021 16:46:19

US3462388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 16:46:58

US3462388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:55
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:58

US3462388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:55
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:58

US3462388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:55
User entered 'patient called but not contacted, message left'	(b) (4), (b) (6)	05 Apr 2021 16:46:58

US3462388

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:47:03

US3462388

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:39:11
User entered 'I'	System	05 Apr 2021 16:47:03

US3462388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:02:36

US3462388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:02:36

US3462388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:02:36

US3462388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	12 Apr 2021 17:02:36

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '08 Apr 2021'	(b) (4) (d) (4), (b) (6)	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '11:50'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User entered '08 Apr 2021 11:50'	System	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '99'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '13'	(b) (4) (d) (4), (b) (6)	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '110'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '74'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 17:03:09

US3462388

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:16

US3462388

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:16

US3462388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:04:00

US3462388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:04:00

US3462388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '11:55'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:04:00

US3462388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 11:55'	System	12 Apr 2021 17:04:00

US3462388

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:04:17

US3462388

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 17:04:17

US3462388

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:01

US3462388

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:01

US3462388

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:01

US3462388

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'UNBLND_DECIDE'	System	30 Mar 2021 22:02:01

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:18

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:18

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:18

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:18

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:18

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:18

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:18

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:18

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:02:18

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered '1'	System	30 Mar 2021 22:02:18

US3462388

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'I'	System	30 Mar 2021 22:02:18

US3462388

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '175' cm	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '80' kg	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered '26.12245'	System	30 Mar 2021 22:03:57
DataPoint set to visible.	System	30 Mar 2021 22:02:18

US3462388

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '175' cm	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '80' kg	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered '26.12245'	System	30 Mar 2021 22:03:57
DataPoint set to visible.	System	30 Mar 2021 22:02:18

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User accepted default value 'Pre-Dose (PREDOSE)'		30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '09:50'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered '3 Mar 2021 09:50'	System	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '77'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'bpm'	System	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '13'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'breaths/min'	System	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '106'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'mmHg'	System	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '70'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'mmHg'	System	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '175' cm	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '80' kg	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered '26.12245'	System	30 Mar 2021 22:03:57
DataPoint set to visible.	System	30 Mar 2021 22:02:18

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User accepted default value 'Post-Dose (POSTDOSE)'		30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '11:37'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered '3 Mar 2021 11:37'	System	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '75'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'bpm'	System	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '14'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'breaths/min'	System	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '101'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'mmHg'	System	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '60'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:03:57

US3462388

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'mmHg'	System	30 Mar 2021 22:03:57

US3462388

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:06

US3462388

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:06

US3462388

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:24

US3462388

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:24

US3462388

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Luck singer (b) (4)	31 Mar 2021 00:06:17
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:24

US3462388

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'mRNA-1273'	System	30 Mar 2021 22:04:24
DataPoint set to visible.	System	30 Mar 2021 22:02:18

US3462388

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:24

US3462388

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '11:00'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:24

US3462388

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered '3 Mar 2021 11:00'	System	30 Mar 2021 22:04:24

US3462388

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:24

US3462388

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'ONCE'	System	30 Mar 2021 22:04:24

US3462388

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'INTRAMUSCULAR'	System	30 Mar 2021 22:04:24

US3462388

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:35

US3462388

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:35

US3462388

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '09:35'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:35

US3462388

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered '3 Mar 2021 09:35'	System	30 Mar 2021 22:04:35

US3462388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:46

US3462388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:46

US3462388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered '09:19'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:46

US3462388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered '3 Mar 2021 09:19'	System	30 Mar 2021 22:04:46

US3462388

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

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:06:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:04:51

US3462388

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

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:04
User entered 'I'	System	30 Mar 2021 22:04:51

US3462388

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:12
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:47:31

US3462388

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:12
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:55
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:47:31

US3462388

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:12
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:47:31

US3462388

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:12
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:55
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 16:47:31

US3462388

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:12
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:20:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:47:37

US3462388

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:12
User entered 'I'	System	05 Apr 2021 16:47:37

US3462388

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:12
User entered '1'	System	05 Apr 2021 16:47:37
DataPoint set to visible.	System	05 Apr 2021 16:47:37

US3462388

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Yes (Y)'	(b) (4) (d) (4), (b) (6)	12 Apr 2021 16:49:41

US3462388

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:49:41

US3462388

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:49:41

US3462388

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	12 Apr 2021 16:49:41

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '11:50'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User entered '08 Apr 2021 11:50'	System	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '99'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '13'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '110'	(b) (4) (d) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '74'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 16:50:26

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '13:22'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User entered '08 Apr 2021 13:22'	System	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered empty.	(b) (4) (d) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '95'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '14'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '115'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '79'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 16:51:23

US3462388

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:35

US3462388

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:51:35

US3462388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:52:31

US3462388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

If No, reason not given

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:52:31

US3462388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:52:31

US3462388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	12 Apr 2021 16:52:31
DataPoint set to visible.	System	05 Apr 2021 16:47:37

US3462388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:52:31

US3462388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered '12:49'	(b) (4) (d) (4), (b) (6)	12 Apr 2021 16:52:31

US3462388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 12:49'	System	12 Apr 2021 16:52:31

US3462388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) System	12 Apr 2021 16:52:43
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	12 Apr 2021 16:52:43
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:52:43
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	12 Apr 2021 16:52:31
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	12 Apr 2021 16:52:31

US3462388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	12 Apr 2021 16:52:31

US3462388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Apr 2021 16:52:31

US3462388

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:46:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:14

US3462388

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 16:54:14

US3462388

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:01

US3462388

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:01

US3462388

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:01

US3462388

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:01

US3462388

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered 'Yes (Y)'	(b) (4) (d) (4), (b) (6)	29 Apr 2021 19:29:06

US3462388

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 19:29:06

US3462388

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered 'Yes (Y)'	(b) (4) (d) (4), (b) (6)	29 Apr 2021 19:29:21

US3462388

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	01 May 2021 11:25:17
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'OOOW' (Site from System).	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
User entered '29 Apr 2021'	(b) (4), (b) (6)	29 Apr 2021 19:29:34
	System	29 Apr 2021 19:29:21
	(b) (4), (b) (6)	29 Apr 2021 19:29:21

US3462388

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:21

US3462388

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Apr 2021 19:29:21

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 19:29:46

US3462388

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:30:16

US3462388

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:30:16

US3462388

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:30:34

US3462388

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	30 Apr 2021 20:07:05
User entered '29 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:30:34

US3462388

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Apr 2021 20:07:05
User entered '10:05'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:30:34

US3462388

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Apr 2021 10:05'	System	29 Apr 2021 19:30:34

US3462388

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:40:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:28:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:39:26
User entered 'Yes (Y)'		07 Oct 2020 17:44:29

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User closed query 'Medical records are not present in subjects binder. Please update subjects binder with hospital records. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:54:39
Query 'Medical records are not present in subjects binder. Please update subjects binder with hospital records. ' answered with 'SAE was verbally reported by patient, but records from hospital have not yet been received to confirm Conmeds/procedures/etc. Requested on 19Oct2020 and 03Nov2020.' (Site from CRA).		06 Nov 2020 19:40:30
DataPoint Verified.		06 Nov 2020 19:00:06
User opened query 'Medical records are not present in subjects binder. Please update subjects binder with hospital records. ' (Site from CRA).		06 Nov 2020 00:49:22
Reviewed for Safety.		08 Oct 2020 13:14:59
User entered 'USA-US093-2020-mRNA-1273-P301000006'	System	08 Oct 2020 13:14:53
User entered 'New'	(b) (4), (b) (6)	08 Oct 2020 13:14:53

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Lower respiratory tract inflammatory and immunologic conditions, PT: Pneumonia aspiration, LLT: Aspiration pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 17:53:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 17:53:12
Data point term sent to Coder	System	07 Oct 2020 17:52:50
User entered 'Aspiration Pneumonia'	(b) (4), (b) (6)	07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'Yes (Y)'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'No (N)'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'No (N)'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered '25 Sep 2020'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Oct 2020 17:52:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 17:52:52
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Oct 2020 17:52:20
User entered '07:45'	(b) (4), (b) (6)	07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 17:52:52
User entered '25 Sep 2020 07:45'	System	07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'No (N)'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered '04 Oct 2020'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	07 Oct 2020 17:52:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 17:52:52
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	07 Oct 2020 17:52:20
User entered '12:00'	(b) (4), (b) (6)	07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 17:52:52
User entered '04 Oct 2020 12:00'	System	07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'Grade 4 (Grade 4)'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'Yes (Y)'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered '0'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered '0'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'I'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered '26 Sep 2020'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	06 Nov 2020 19:00:06
User entered '04 Oct 2020'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'No (N)'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	06 Nov 2020 19:00:06
User entered empty.		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered '0'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered '0'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered '0'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'Not Related (NOT RELATED)'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'Not Related (NOT RELATED)'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'None (NONE)'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered '0'		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User closed query 'Per CDM re-query: Thank you for the information. Please provide the response once the contact made and Con med recorded in CM eCRF else respond to clarify. Thank you' (Site from DM). Query 'Per CDM re-query: Thank you for the information. Please provide the response once the contact made and Con med recorded in CM eCRF else respond to clarify. Thank you' answered with 'Records requested 3 times but none received. No records available.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 16:15:50
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).		02 Feb 2021 19:01:09
User opened query 'Per CDM re-query: Thank you for the information. Please provide the response once the contact made and Con med recorded in CM eCRF else respond to clarify. Thank you' (Site from DM).		19 Nov 2020 08:08:30
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'Conmed was verbally reported by patient, but records from hospital have not yet been received to confirm name/dosage/etc. Requested on 19Oct2020 and 03Nov2020.' (Site from DM).		19 Nov 2020 08:08:27
DataPoint Verified.		06 Nov 2020 19:31:44
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).		06 Nov 2020 19:00:06
User entered 'I'		29 Oct 2020 00:17:21
		07 Oct 2020 17:52:20

US3462388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User closed query 'Per CDM re-query: Thank you for the information. Please provide the response once the contact made and Con Proc recorded in Con Proc eCRF else respond to clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:15:52
Query 'Per CDM re-query: Thank you for the information. Please provide the response once the contact made and Con Proc recorded in Con Proc eCRF else respond to clarify. Thank you' answered with 'Records requested 3 times but none received. No records available.' (Site from DM).		02 Feb 2021 19:01:11
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).		19 Nov 2020 08:09:18
User opened query 'Per CDM re-query: Thank you for the information. Please provide the response once the contact made and Con Proc recorded in Con Proc eCRF else respond to clarify. Thank you' (Site from DM).		19 Nov 2020 08:09:12
DataPoint Un-verified.		18 Nov 2020 00:11:31
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'SAE was verbally reported by patient, but records from hospital have not yet been received to confirm procedures performed. Requested on 19Oct2020 and 03Nov2020.' (Site from DM).		06 Nov 2020 19:33:11
DataPoint Verified.		06 Nov 2020 19:00:06

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). User entered '1'	(b) (4), (b) (6)	29 Oct 2020 00:17:31
		07 Oct 2020 17:52:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:00:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		07 Oct 2020 17:52:20

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	06 Nov 2020 19:00:06
User entered empty.		07 Oct 2020 17:52:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luckinger (b) (4)	19 Feb 2021 20:42:31
User closed query 'PV Query: Please provide information regarding the patients presenting signs/symptoms including exam findings and vital signs, and clinical course while hospitalized. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:26:39
User closed query 'PV Query: Please provide results of any laboratory studies and cultures done to evaluate the event. ' (Site from Safety).		03 Feb 2021 17:26:37
User closed query 'PV Query: Please provide results of covid testing done while hospitalized. If not performed, please state this. ' (Site from Safety).		03 Feb 2021 17:26:35
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).		03 Feb 2021 17:26:33
User closed query 'Per DM RQ: Thank you for the response. Once hospital records are received, please update ConProc appropriately. ' (Site from DM).		03 Feb 2021 16:16:04
Query 'Per DM RQ: Thank you for the response. Once hospital records are received, please update ConProc appropriately. ' answered with 'Records requested 3 times but none received. No records available.' (Site from DM).		02 Feb 2021 19:00:59
Query 'PV Query: Please provide information regarding the patients presenting signs/symptoms including exam findings and vital signs, and clinical course while hospitalized. ' answered with 'Records requested 3 times but none received. No records available.' (Site from Safety).		02 Feb 2021 19:00:56
Query 'PV Query: Please provide results of any laboratory studies and cultures done to evaluate the event. ' answered with 'Records requested 3 times but none received. No records available.' (Site from Safety).		02 Feb 2021 19:00:53

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide results of covid testing done while hospitalized. If not performed, please state this. ' answered with 'Records requested 3 times but none received. No records available.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 19:00:51
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' answered with 'Records requested 3 times but none received. No records available.' (Site from Safety).		02 Feb 2021 19:00:48
User opened query 'Per DM RQ: Thank you for the response. Once hospital records are received, please update ConProc appropriately. ' (Site from DM).		23 Nov 2020 13:41:03
User closed query 'Per DM CLR: SAE Narrative indicates that the subject underwent Head CT. However, there is no corresponding ConProc record that match this information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).		23 Nov 2020 13:41:03
User opened query 'PV Query: Please provide information regarding the patients presenting signs/symptoms including exam findings and vital signs, and clinical course while hospitalized. ' (Site from Safety).		10 Nov 2020 13:28:48
User opened query 'PV Query: Please provide results of any laboratory studies and cultures done to evaluate the event. ' (Site from Safety).		10 Nov 2020 13:28:35
User opened query 'PV Query: Please provide results of covid testing done while hospitalized. If not performed, please state this. ' (Site from Safety).		10 Nov 2020 13:28:25
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).		10 Nov 2020 13:28:12

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide information regarding the patients presenting signs/symptoms including exam findings and vital signs, and clinical course while hospitalized.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 17:20:09
User closed query 'PV query: Please provide results of any laboratory studies and cultures done to evaluate the event.' (Site from Safety).		09 Nov 2020 17:20:07
User closed query 'PV query: Please provide results of covid testing done while hospitalized. If not performed, please state this.' (Site from Safety).		09 Nov 2020 17:20:05
User closed query 'PV Query: Please confirm concomitant medication for hypercholesterolemia as it was reported as "Avostatin" (Site from Safety).		09 Nov 2020 17:20:03
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).		09 Nov 2020 17:19:59
Query 'Per DM CLR: SAE Narrative indicates that the subject underwent Head CT. However, there is no corresponding ConProc record that match this information. Please update to record the procedure as appropriate. Otherwise, clarify.' answered with 'SAE was verbally reported by patient, but records from hospital have not yet been received to confirm Conmeds/procedures/etc. Requested on 19Oct2020 and 03Nov2020.' (Site from DM).		06 Nov 2020 19:37:21
Query 'PV query: Please provide information regarding the patients presenting signs/symptoms including exam findings and vital signs, and clinical course while hospitalized.' answered with 'SAE was verbally reported by patient, but records from hospital have not yet been received to confirm Conmeds/procedures/etc. Requested on 19Oct2020 and 03Nov2020.' (Site from Safety).		06 Nov 2020 19:37:11

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide results of any laboratory studies and cultures done to evaluate the event.' answered with 'SAE was verbally reported by patient, but records from hospital have not yet been received to confirm Conmeds/procedures/etc. Requested on 19Oct2020 and 03Nov2020.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:36:47
Query 'PV query: Please provide results of covid testing done while hospitalized. If not performed, please state this.' answered with 'SAE was verbally reported by patient, but records from hospital have not yet been received to confirm Conmeds/procedures/etc. Requested on 19Oct2020 and 03Nov2020.' (Site from Safety).		06 Nov 2020 19:36:40
Query 'PV Query: Please confirm concomitant medication for hypercholesterolemia as it was reported as "Avostatin"' answered with 'Corrected.' (Site from Safety).		06 Nov 2020 19:36:18
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'SAE was verbally reported by patient, but records from hospital have not yet been received to confirm Conmeds/procedures/etc. Requested on 19Oct2020 and 03Nov2020.' (Site from Safety).		06 Nov 2020 19:34:26
DataPoint Verified.		06 Nov 2020 19:00:06
User opened query 'Per DM CLR: SAE Narrative indicates that the subject underwent Head CT. However, there is no corresponding ConProc record that match this information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).		29 Oct 2020 00:18:26
User opened query 'PV query: Please provide information regarding the patients presenting signs/symptoms including exam findings and vital signs, and clinical course while hospitalized.' (Site from Safety).		16 Oct 2020 15:19:56

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide results of any laboratory studies and cultures done to evaluate the event.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:19:37
User opened query 'PV query: Please provide results of covid testing done while hospitalized. If not performed, please state this.' (Site from Safety).		16 Oct 2020 15:19:26
User opened query 'PV Query: Please confirm concomitant medication for hypercholesterolemia as it was reported as "Avostatin"' (Site from Safety).		16 Oct 2020 15:19:14
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).		16 Oct 2020 15:19:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT IS A 46 YEAR OLD MALE WITH HYPERCHOLESTEROLEMIA AND DEPRESSION. ON 25SEP2020 WHILE EATING, HE ASPIRATED ON A PIECE OF FOOD AND HAD COUGHING THROUGHOUT THAT DAY. HE ALSO COUGHED THROUGH THE NIGHT. THE NEXT MORNING, 26SEP2020, AT WORK HE HAD A SYNCOPAL EPISODE. EMS WAS ACTIVATED AND HE WAS EVALUATED IN THE EMERGENCY DEPARTMENT. CHEST IMAGING SHOWED PULMONARY INFILTRATE AND WAS TREATED FOR ASPIRATION PNEUMONIA WITH ANTIBIOTICS. HE REMAINED IN THE HOSPITAL FOR 8 DAYS (26SEP2020-04OCT2020). HE ALSO HAD A HEAD CT TO EVALUATE FOR STROKE, NONE WAS SEEN. PATIENT DISCHARGED 04OCT2020. PATIENT WAS CONSENTED/SCREENED/AND RANDOMIZED TO STUDY 31AUG2020. HE HAD HIS FIRST IP INJECTION ON THAT DAY. HE DID NOT RECEIVE HIS SECOND IP INJECTION AS HE WAS HOSPITALIZED. WE WERE NOTIFIED OF THESE EVENTS 07OCT2020. SAE OF ASPIRATION PNEUMONIA NOT RELATED TO STUDY IP. PATIENT RECOVERED AND PLANS TO RETURN TO CONTINUE STUDY NEXT WEEK.' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:14:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient is a 46 year old male with hypercholesterolemia and depression.. On 25SEP2020 while eating, he aspirated on a piece of food and had coughing throughout that day. He also coughed through the night. The next morning, 26SEP2020, at work he had a syncopal episode. EMS was activated and he was evaluated in the emergency department. Chest imaging showed pulmonary infiltrate and was treated for aspiration pneumonia with antibiotics. He remained in the hospital for 8 days (26SEP2020-04OCT2020). He also had a head CT to evaluate for stroke, none was seen. Patient discharged 04OCT2020. Patient was consented/screened/and Randomized to study 31AUG2020. He had his first IP injection on that day. He did not receive his second IP injection as he was hospitalized. We were notified of these events 07OCT2020. SAE of aspiration pneumonia not related to study IP. Patient recovered and plans to return to continue study next week.'	(b) (4), (b) (6)	07 Oct 2020 17:52:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 17:52:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Oct 2020 17:52:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 17:52:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:18:39
User entered 'USA-US093-2020-mRNA-1273-P301000006'		05 Mar 2021 19:18:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 18:35:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 18:35:09
Data point term sent to Coder	System	04 Mar 2021 18:34:38
User entered 'Myocardial Infarction'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'PV Query: Please confirm onset date as angiogram was not performed until 02 Dec 2020. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:05:56
Query 'PV Query: Please confirm onset date as angiogram was not performed until 02 Dec 2020. ' answered with 'Per narrative and progress note, date is correct' (Site from Safety).		14 Apr 2021 16:55:34
User opened query 'PV Query: Please confirm onset date as angiogram was not performed until 02 Dec 2020. ' (Site from Safety).		11 Mar 2021 18:22:28
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	04 Mar 2021 19:00:53
User entered '25 Sep 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Mar 2021 19:00:53
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	04 Mar 2021 18:34:04
User entered '25 Sep 2021'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	04 Mar 2021 19:00:53
User entered '25 Sep 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Mar 2021 19:00:53
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	04 Mar 2021 18:34:04
User entered '25 Sep 2021'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
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	04 Mar 2021 19:00:53
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	04 Mar 2021 18:34:04
User entered 'Yes (Y)'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
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)	04 Mar 2021 19:00:53
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).		04 Mar 2021 19:00:53
User entered '1' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Mar 2021 19:00:53
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	04 Mar 2021 18:34:04
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant). ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:06:02
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant). ' answered with 'Per progress notes patient was hospitalized from 25Sep20 to 04Oct20' (Site from Safety).		14 Apr 2021 17:16:24
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant). ' (Site from Safety).		11 Mar 2021 18:21:58
User entered '25 Sep 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '25 Sep 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	15 Apr 2021 19:50:42
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		15 Apr 2021 19:50:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 19:50:42
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Mar 2021 18:34:04
User entered 'Unknown (UNK)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

US3462388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

US3462388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'None (NONE)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

US3462388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '1'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

US3462388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

US3462388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "ANGIOGRAM & SINGLE BYPASS SURGERY." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 11:12:45
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed 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. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:06:54
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 'unable to obtain' (Site from Safety).		15 Apr 2021 19:50:21
Query 'Per DM CLR: Narrative indicates that subject had "ANGIOGRAM & SINGLE BYPASS SURGERY." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'PROCEDURES ADDED TO EDC' (Site from DM).		14 Apr 2021 17:31:30
User opened query 'Per DM CLR: Narrative indicates that subject had "ANGIOGRAM & SINGLE BYPASS SURGERY." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		25 Mar 2021 05:11:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User opened 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. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:22:52
User entered 'Subject is a 46 year old male with previously reported SAE of Aspiration Pneumonia that occurred 25SEP2020-04OCT2020. Subject had no diagnosis of any heart related conditions at time of this hospitalization, however, he did have ongoing suspicion that this event was heart related. Therefore, subject reached out to a local cardiologist in December 2020. Cardiologist ordered an angiogram be performed on approximately 02DEC2020. Angiogram reveled that subject had Severe Arthrosclerosis of one of the main arteries going into the heart and subject reported that cardiologist diagnosed event on 25SEP2020 as also being Myocardial Infarction. Therefore, single bypass surgery was scheduled and performed on 11DEC2020. Subject reported that surgery was performed without complication and subject was discharged on approximately 14DEC2020. All event details were obtained via subject verbal report at Visit 4.'	Danuel Hamlin (b) (4)	04 Mar 2021 18:34:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 18:34:04

US3462388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:34:04

US3462388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 18:34:04

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:19:15
User entered 'USA-US093-2020-mRNA-1273-P301000006'		05 Mar 2021 19:19:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Joint stiffness, LLT: Arthrosclerosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Mar 2021 05:19:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 05:19:52
Data point term sent to Coder	System	04 Mar 2021 18:36:39
User entered 'Severe Arthrosclerosis'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'PV Query: Please confirm onset date as angiogram was not performed until 02 Dec 2020. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:06:09
Query 'PV Query: Please confirm onset date as angiogram was not performed until 02 Dec 2020. ' answered with 'per narrative and progress notes start date is correct' (Site from Safety).		14 Apr 2021 17:32:51
User opened query 'PV Query: Please confirm onset date as angiogram was not performed until 02 Dec 2020. ' (Site from Safety).		11 Mar 2021 18:23:21
User entered '25 Sep 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	04 Mar 2021 19:01:24
User entered 'No (N)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Mar 2021 19:01:24
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	04 Mar 2021 18:36:15
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '11 Dec 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '1'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '11 Dec 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '14 Dec 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	15 Apr 2021 19:52:04
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		15 Apr 2021 19:52:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 19:52:04
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Mar 2021 18:36:15
User entered 'Unknown (UNK)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'None (NONE)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	15 Apr 2021 19:53:20
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 19:53:20
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	15 Apr 2021 19:52:29
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 19:52:29
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 11:38:51
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM). User entered '0' reason for change: Data Entry Error	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	15 Apr 2021 21:14:02 15 Apr 2021 19:53:00 15 Apr 2021 19:52:04
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). User entered '1'	(b) (4) Danuel Hamlin (b) (4)	25 Mar 2021 05:11:57 04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '1'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed 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. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:07:21
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 'unable to obtain' (Site from Safety).		15 Apr 2021 19:51:25
User opened 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. ' (Site from Safety).		11 Mar 2021 18:23:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject is a 46 year old male with previously reported SAE of Aspiration Pneumonia that occurred 25SEP2020-04OCT2020. Subject had no diagnosis of any heart related conditions at time of this hospitalization, however, he did have ongoing suspicion that this event was heart related. Therefore, subject reached out to a local cardiologist in December 2020. Cardiologist ordered an angiogram be performed on approximately 02DEC2020. Angiogram reveled that subject had Severe Arthrosclerosis of one of the main arteries going into the heart and subject reported that cardiologist diagnosed event on 25SEP2020 as also being Myocardial Infarction. Therefore, single bypass surgery was scheduled and performed on 11DEC2020. Subject reported that surgery was performed without complication and subject was discharged on approximately 14DEC2020. All event details were obtained via subject verbal report at Visit 4.'	Danuel Hamlin (b) (4)	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:36:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 18:36:15

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:33:34
User entered 'USA-US093-2020-mRNA-1273-P301000006'		05 Mar 2021 19:33:31

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User coded data point as SOC: Cardiac disorders, HLT: Pericardial disorders, HLT: Noninfectious pericarditis, PT: Pericarditis, LLT: Pericarditis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:42:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:42:30
Data point term sent to Coder	System	04 Mar 2021 18:46:47
User entered 'Post Surgical Pericarditis Secondary to Coronary Bypass Surgery'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '28 Dec 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'PV Query: Please confirm event end date as this was the first occurrence of post-surgical pericarditis. ' (Site from Safety).	(b) (4)	15 Apr 2021 19:06:18
Query 'PV Query: Please confirm event end date as this was the first occurrence of post-surgical pericarditis. ' answered with 'End date correct per source document ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 17:39:05
User entered '30 Dec 2020' reason for change: Data Entry Error		14 Apr 2021 17:38:25
User opened query 'PV Query: Please confirm event end date as this was the first occurrence of post-surgical pericarditis. ' (Site from Safety).		11 Mar 2021 18:24:30
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	04 Mar 2021 19:02:06
User entered '26 Jan 2021' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Mar 2021 19:02:06
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	04 Mar 2021 18:46:38
User entered '26 Jan 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '1'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '28 Dec 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '30 Dec 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	15 Apr 2021 19:59:45
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	15 Apr 2021 19:59:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 19:59:45
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Mar 2021 18:46:38
User entered 'Unknown (UNK)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4)	15 Apr 2021 20:08:04
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 20:00:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		15 Apr 2021 19:59:45
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).		11 Mar 2021 18:25:04
User entered 'None (NONE)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '1'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User opened 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. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:25:20
User entered 'Subject is a 46 year old male with previously reported SAE of Aspiration Pneumonia that occurred 25SEP2020-04OCT2020. Subject had no diagnosis of any heart related conditions at time of this hospitalization, however, he did have ongoing suspicion that this event was heart related. Therefore, subject reached out to a local cardiologist in December 2020. Cardiologist ordered an angiogram be performed on approximately 02DEC2020. Angiogram reveled that subject had Severe Arthrosclerosis of one of the main arteries going into the heart and subject reported that cardiologist diagnosed event on 25SEP2020 as also being Myocardial Infarction. Therefore, single bypass surgery was scheduled and performed on 11DEC2020. Subject reported that surgery was performed without complication and subject was discharged on approximately 14DEC2020. All event details were obtained via subject verbal report at Visit 4.	Danuel Hamlin (b) (4)	04 Mar 2021 18:46:38
Following surgery, subject had continued shortness of breath and therefore, went to the ER on 28DEC2020 and was diagnosed with post-surgical pericarditis and pleural effusion both secondary to coronary bypass surgery . Subject reported that fluid was drained from heart and from lungs. Subject stated that procedures were performed without complication and subject was discharged on approximately 30DEC2020.'		

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 18:46:38

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:05
User entered 'USA-US093-2020-mRNA-1273-P301000006'		05 Mar 2021 19:34:03

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:43:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:43:29
Data point term sent to Coder	System	04 Mar 2021 18:48:50
User entered 'Post Surgical Pleural Effusion'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '28 Dec 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'PV Query: It was noted that subject was admitted again due to ongoing post-surgical pericarditis and pleural effusion on 14 Jan 2021. However, post surgical pleural effusion was reported as resolved on 30 Dec 2020. Please confirm if post surgical pleural effusion end date should be updated as subject was readmitted on 14 Jan 2021. ' (Site from Safety). Query 'PV Query: It was noted that subject was admitted again due to ongoing post-surgical pericarditis and pleural effusion on 14 Jan 2021. However, post surgical pleural effusion was reported as resolved on 30 Dec 2020. Please confirm if post surgical pleural effusion end date should be updated as subject was readmitted on 14 Jan 2021. ' answered with 'date is correct' (Site from Safety). User opened query 'PV Query: It was noted that subject was admitted again due to ongoing post-surgical pericarditis and pleural effusion on 14 Jan 2021. However, post surgical pleural effusion was reported as resolved on 30 Dec 2020. Please confirm if post surgical pleural effusion end date should be updated as subject was readmitted on 14 Jan 2021. ' (Site from Safety). User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:09:23 15 Apr 2021 20:02:59 11 Mar 2021 18:26:30
	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '1'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '28 Dec 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '30 Dec 2020'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	(b) (4) System	15 Apr 2021 20:02:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 20:02:44
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Mar 2021 19:07:15
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Mar 2021 19:07:15
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	04 Mar 2021 19:02:44
User entered 'No (N)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Mar 2021 19:02:44
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Mar 2021 18:48:33
User entered 'Unknown (UNK)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4)	15 Apr 2021 20:09:30
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 20:03:07
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		15 Apr 2021 20:02:44
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).		11 Mar 2021 18:26:57
User entered 'None (NONE)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '1'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "FLUID WAS DRAINED." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 11:15:24
User closed 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. ' (Site from Safety). 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 'unable to obtain' (Site from Safety). Query 'Per DM CLR: Narrative indicates that subject had "FLUID WAS DRAINED." However, this information is 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). User opened query 'Per DM CLR: Narrative indicates that subject had "FLUID WAS DRAINED." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	15 Apr 2021 21:14:02 15 Apr 2021 20:09:27 15 Apr 2021 20:02:26 15 Apr 2021 20:02:23 25 Mar 2021 05:12:22

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User opened 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. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:27:14
User entered 'Following surgery, subject had continued shortness of breath and therefore, went to the ER on 28DEC2020 and was diagnosed with post-surgical pericarditis and pleural effusion both secondary to coronary bypass surgery . Subject reported that fluid was drained from heart and from lungs. Subject stated that procedures were performed without complication and subject was discharged on approximately 30DEC2020.'	Danuel Hamlin (b) (4)	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 18:48:33

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:36:50
User entered 'USA-US093-2020-mRNA-1273-P301000006'		05 Mar 2021 19:36:45

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User coded data point as SOC: Cardiac disorders, HLT: Pericardial disorders, HLT: Noninfectious pericarditis, PT: Pericarditis, LLT: Pericarditis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:45:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:45:45
Data point term sent to Coder	System	04 Mar 2021 18:54:55
User entered 'Post-Surgical Pericarditis Secondary to Coronary Bypass Surgery'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 19:07:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 19:07:42
User entered 'No (N)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Mar 2021 19:07:42
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 18:54:12
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '14 Jan 2021'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '20 Jan 2021'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'I'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '14 Jan 2021'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '20 Jan 2021'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	15 Apr 2021 20:03:55
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		15 Apr 2021 20:03:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 20:03:55
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Mar 2021 18:54:12
User entered 'Unknown (UNK)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:08:58
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'updated' (Site from Safety).		15 Apr 2021 20:04:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		15 Apr 2021 20:03:55
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).		11 Mar 2021 18:27:57
User entered 'None (NONE)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '1'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "FLUID WAS DRAINED." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Gregg Lucksinger (b) (4)	16 Apr 2021 11:16:37 15 Apr 2021 21:14:02
User closed 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. ' (Site from Safety). Query 'Per DM CLR: Narrative indicates that subject had "FLUID WAS DRAINED." However, this information is 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). 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 'unable to obtain' (Site from Safety). User opened query 'Per DM CLR: Narrative indicates that subject had "FLUID WAS DRAINED." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 20:09:02 15 Apr 2021 20:03:27 15 Apr 2021 20:03:20 25 Mar 2021 05:12:32

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User opened 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. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:27:40
User entered 'Following surgery, subject had continued shortness of breath and therefore, went to the ER on 28DEC2020 and was diagnosed with post-surgical pericarditis and pleural effusion both secondary to coronary bypass surgery . Subject reported that fluid was drained from heart and from lungs. Subject stated that procedures were performed without complication and subject was discharged on approximately 30DEC2020.	Danuel Hamlin (b) (4)	04 Mar 2021 18:54:12

Subject continued to have shortness of breath and therefore, went back to ER on approximately 14JAN2021. Subject admitted again due to ongoing post-surgical pericarditis and pleural effusion. Subject had pericardial window procedure performed. Procedure was performed without complication and subject was discharged on approximately 20JAN2021.'

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 18:54:12

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:37:28
User entered 'USA-US093-2020-mRNA-1273-P301000006'		05 Mar 2021 19:37:25

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User coded data point as SOC: Cardiac disorders, HLT: Pericardial disorders, HLT: Noninfectious pericarditis, PT: Pericarditis, LLT: Pericarditis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:42:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:42:31
Data point term sent to Coder	System	04 Mar 2021 18:59:59
User entered 'Post Surgical Pericarditis secondary to Coronary Bypass Surgery'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '26 Jan 2021'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '30 Jan 2021'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '1'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '26 Jan 2021'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '30 Jan 2021'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	15 Apr 2021 20:04:47
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		15 Apr 2021 20:04:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 20:04:47
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Mar 2021 18:59:26
User entered 'Unknown (UNK)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4)	15 Apr 2021 20:08:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 20:04:47
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'updated' (Site from Safety).		15 Apr 2021 20:04:18
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).		11 Mar 2021 18:28:23
User entered 'None (NONE)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '0'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered '1'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
	(b) (4)	
User entered empty.	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "FLUID WAS DRAINED." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 11:16:47
User closed 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. ' (Site from Safety). 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 'unable to obtain' (Site from Safety). Query 'Per DM CLR: Narrative indicates that subject had "FLUID WAS DRAINED." However, this information is 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). User opened query 'Per DM CLR: Narrative indicates that subject had "FLUID WAS DRAINED." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	Gregg Lucksinger (b) (4) (b) (4), (b) (6)	15 Apr 2021 21:14:02 15 Apr 2021 20:08:44 15 Apr 2021 20:04:32 15 Apr 2021 20:04:28 25 Mar 2021 05:12:42

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Narrative](#)

Audit	User	Time (GMT)
User opened 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. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 18:28:32
User entered 'Subject continued to have shortness of breath and therefore, went back to ER on approximately 14JAN2021. Subject admitted again due to ongoing post-surgical pericarditis and pleural effusion. Subject had pericardial window procedure performed. Procedure was performed without complication and subject was discharged on approximately 20JAN2021. Following this procedure, Subject continued to have shortness of breath and returned for second pericardial window procedure on approximately 26JAN2021. Subject reported that procedure was performed without complication and subject was discharged on approximately 30JAN2021. All hospitalization details were obtained via subject verbal report. We will confirm details following receipt of hospital records.'	Danuel Hamlin (b) (4)	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 18:59:26

US3462388

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:40:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 18:59:26

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:40:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:28:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User closed query 'Per ETRTR: According to SAE "Aspiration Pneumonia" CRF, Concomitant Medication and Concomitant Procedures were done. Please Update ConMeds and ConProcedures pages accordingly, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 21:03:35
Query 'Per ETRTR: According to SAE "Aspiration Pneumonia" CRF, Concomitant Medication and Concomitant Procedures were done. Please Update ConMeds and ConProcedures pages accordingly, thanks.' answered with 'SAE was verbally reported b patient, but records from hospital have not yet been received to confirm Conmeds/procedures/etc. Requested on 19Oct2020 and 03Nov2020.' (Site from CRA).		06 Nov 2020 19:40:49
User opened query 'Per ETRTR: According to SAE "Aspiration Pneumonia" CRF, Concomitant Medication and Concomitant Procedures were done. Please Update ConMeds and ConProcedures pages accordingly, thanks.' (Site from CRA).		10 Oct 2020 22:39:32
User entered 'Yes (Y)'		01 Sep 2020 01:34:40

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:02:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:02:43
Data point term sent to Coder	System	01 Sep 2020 01:36:11
User entered 'NORCO (5/325)'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)' reason for change: Data Entry Error		13 Oct 2020 03:32:46
User entered 'Yes (Y)'		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'LOWER BACK PAIN'		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'I'		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'tablet (TABLET)'		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'once daily (QD)'		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Oral (ORAL)'		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'UN Mar 2020'		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '0'		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Yes (Y)'		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)'		01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 01:35:28

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:26:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:26:42
Data point term sent to Coder	System	01 Sep 2020 01:37:11
User entered 'GABAPENTIN'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)' reason for change: Data Entry Error		12 Oct 2020 17:54:00
User entered 'Yes (Y)'		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		13 Oct 2020 13:15:50
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).		12 Oct 2020 17:54:16
User opened query 'Per DM CLR: Prophylaxis = Yes however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		12 Oct 2020 10:55:15
User entered 'TOURETTS SYNDROME'		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '400'		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'mg (mg)'		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'once daily (QD)'		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Oral (ORAL)'		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'UN UNK 2017'		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '0'		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Yes (Y)'		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)'		01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 01:36:41

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: DIAZEPAM, PRODUCTSYNONYM: VALIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:42:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:42:42
Data point term sent to Coder	System	01 Sep 2020 01:38:12
User entered 'VALIUM'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)' reason for change: Data Entry Error		12 Oct 2020 17:54:30
User entered 'Yes (Y)'		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		13 Oct 2020 13:15:57
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).		12 Oct 2020 17:54:36
User opened query 'Per DM CLR: Prophylaxis = Yes however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		12 Oct 2020 10:55:30
User entered 'TOURETTES SYNDROME'		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '10'		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'mg (mg)'		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'twice daily (BID)'		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Oral (ORAL)'		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'UN Mar 2020'		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '0'		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Yes (Y)'		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)'		01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 01:37:31

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:16:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:16:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:01:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:01:41
Data point term sent to Coder User entered 'NEXIUM'	System (b) (4), (b) (6)	01 Sep 2020 01:38:12 01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)' reason for change: Data Entry Error		12 Oct 2020 17:55:16
User entered 'Yes (Y)'		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		13 Oct 2020 13:16:04
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).		12 Oct 2020 17:55:20
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		12 Oct 2020 10:56:01
User entered 'OCCASIONAL ACID REFLUX'		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '40'		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'mg (mg)'		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'once daily (QD)'		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Oral (ORAL)'		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'UN UNK 2019'		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '0'		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Yes (Y)'		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)'		01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 01:38:03

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 01:40:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 01:40:41
Data point term sent to Coder	System	01 Sep 2020 01:39:13
User entered 'ZOLOFT'	(b) (4), (b) (6)	01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)' reason for change: Data Entry Error		12 Oct 2020 17:55:28
User entered 'Yes (Y)'		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		13 Oct 2020 13:16:09
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).		12 Oct 2020 17:55:32
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		12 Oct 2020 10:56:35
User entered 'DEPRESSION'		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '200'		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'mg (mg)'		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'once daily (QD)'		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Oral (ORAL)'		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'UN UNK 2015'		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '0'		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Yes (Y)'		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)'		01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 01:38:32

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 19:36:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:36:20
Data point term sent to Coder DataPoint Un-verified.	System (b) (4), (b) (6)	06 Nov 2020 19:35:35 06 Nov 2020 19:35:16
Coding entries removed.		06 Nov 2020 19:35:16
User entered 'AtorVaSTATIN' reason for change: Data Entry Error		06 Nov 2020 19:35:16
DataPoint Verified.		06 Nov 2020 00:42:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM, PRODUCTSYNONYM: AVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:58:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:58:42
Data point term sent to Coder User entered 'AVOSTATIN'	System (b) (4), (b) (6)	01 Sep 2020 01:39:13 01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)' reason for change: Data Entry Error		12 Oct 2020 17:55:39
User entered 'Yes (Y)'		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		13 Oct 2020 13:16:17
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).		12 Oct 2020 17:55:43
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		12 Oct 2020 10:56:48
User entered 'HYPERCHOLESTEROLEMIA'		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '20'		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'mg (mg)'		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'once daily (QD)'		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Oral (ORAL)'		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'UN UNK 2019'		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	06 Nov 2020 00:42:54
User entered '0'		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'Yes (Y)'		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered empty.		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:42:54
User entered 'No (N)'		01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 01:38:57

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:40:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:28:05
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:05:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 17:28:01

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:05:29
User entered '02 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:28:44

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:05:29
User entered 'ANGIOGRAM'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:28:44

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:05:29
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:28:44

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:05:29
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:28:44

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:38
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:05:29
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:29:06

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:38
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:05:29
User entered 'SINGLE BYPASS SURGERY'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:29:06

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:38
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:05:29
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	14 Apr 2021 17:29:06

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:38
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 05:05:29
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:29:06

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:40:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:39
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:01:53

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:40:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:39
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User entered 'Fluid draining from heart and lungs'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:01:53

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:40:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:39
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:01:53

US3462388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:40:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:39
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:01:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'USA-US093-2020-MRNA-1273-P301000006'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Gregg'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Edward'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Lucksinger'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Kerwin'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '1900 Cypress Creek Rd'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'Cedar Park'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'TX'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '78613'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 19:19:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
User entered 'US'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 13:18:26
User entered '5'	System	15 Apr 2021 20:02:29
User entered '4'	System	15 Apr 2021 19:07:09
User entered '3'	System	05 Mar 2021 19:40:55
User entered '2'	System	05 Mar 2021 19:19:50
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
	(b) (4)	
User entered '1'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'USA-US093-2020-MRNA-1273-P301000006'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Gregg'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Edward'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Lucksinger'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Kerwin'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '1900 Cypress Creek Rd'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'Cedar Park'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'TX'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '78613'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 19:19:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
User entered 'US'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 13:18:26
User entered '5'	System	15 Apr 2021 20:02:29
User entered '4'	System	15 Apr 2021 19:07:09
User entered '3'	System	05 Mar 2021 19:40:55
User entered '2'	System	05 Mar 2021 19:19:50
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
	(b) (4)	
User entered '1'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
User entered '08/Oct/2020 13:25'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 19:19:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
User entered 'I'		08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'USA-US093-2020-MRNA-1273-P301000006'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Gregg'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Edward'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Lucksinger'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Kerwin'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '1900 Cypress Creek Rd'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'Cedar Park'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'TX'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '78613'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 19:19:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
User entered 'US'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 13:18:26
User entered '5'	System	15 Apr 2021 20:02:29
User entered '4'	System	15 Apr 2021 19:07:09
User entered '3'	System	05 Mar 2021 19:40:55
User entered '2'	System	05 Mar 2021 19:19:50
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
	(b) (4)	
User entered '1'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:52
User entered '05/Mar/2021 14:19'	(b) (4) System	05 Mar 2021 19:19:50

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:40:36
User entered 'I'		05 Mar 2021 19:19:50

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'USA-US093-2020-MRNA-1273-P301000006'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Gregg'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Edward'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Lucksinger'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Kerwin'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '1900 Cypress Creek Rd'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'Cedar Park'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'TX'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '78613'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 19:19:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
User entered 'US'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 13:18:26
User entered '5'	System	15 Apr 2021 20:02:29
User entered '4'	System	15 Apr 2021 19:07:09
User entered '3'	System	05 Mar 2021 19:40:55
User entered '2'	System	05 Mar 2021 19:19:50
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
	(b) (4)	
User entered '1'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:40:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:52
User entered '05/Mar/2021 14:40'	(b) (4) System	05 Mar 2021 19:40:55

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:40:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:06:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:52
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 19:40:55

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'USA-US093-2020-MRNA-1273-P301000006'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Gregg'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Edward'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Lucksinger'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Kerwin'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '1900 Cypress Creek Rd'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'Cedar Park'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'TX'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '78613'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 19:19:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
User entered 'US'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 13:18:26
User entered '5'	System	15 Apr 2021 20:02:29
User entered '4'	System	15 Apr 2021 19:07:09
User entered '3'	System	05 Mar 2021 19:40:55
User entered '2'	System	05 Mar 2021 19:19:50
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
	(b) (4)	
User entered '1'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:40:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User entered '15/Apr/2021 14:06'	(b) (4) System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:40:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'I'		15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'USA-US093-2020-MRNA-1273-P301000006'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Gregg'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Edward'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Lucksinger'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Kerwin'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '1900 Cypress Creek Rd'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'Cedar Park'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'TX'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '78613'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 19:19:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
User entered 'US'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 13:18:26
User entered '5'	System	15 Apr 2021 20:02:29
User entered '4'	System	15 Apr 2021 19:07:09
User entered '3'	System	05 Mar 2021 19:40:55
User entered '2'	System	05 Mar 2021 19:19:50
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
	(b) (4)	
User entered '1'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:40:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User entered '15/Apr/2021 16:02'	(b) (4) System	15 Apr 2021 20:02:29

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:40:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:18:01
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 20:02:29

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'USA-US093-2020-MRNA-1273-P301000006'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Yes (Y)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'No (N)'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Gregg'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Edward'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
Un-reviewed for Safety.	System	15 Apr 2021 19:07:09
DataPoint Un-verified.	System	15 Apr 2021 19:07:09
Signature has been broken.	System	15 Apr 2021 19:07:09
User entered 'Lucksinger'	System	15 Apr 2021 19:07:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
Reviewed for Safety.		08 Oct 2020 13:25:44
User entered 'Kerwin'	System	08 Oct 2020 13:14:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '1900 Cypress Creek Rd'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'Cedar Park'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered 'TX'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:02:04
User entered '78613'	System	15 Apr 2021 19:07:09

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 19:19:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:38:01
User entered 'US'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 13:18:26
User entered '5'	System	15 Apr 2021 20:02:29
User entered '4'	System	15 Apr 2021 19:07:09
User entered '3'	System	05 Mar 2021 19:40:55
User entered '2'	System	05 Mar 2021 19:19:50
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:42:31
	(b) (4)	
User entered '1'	System	08 Oct 2020 13:25:53

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:40:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:40
User entered '16/Apr/2021 13:18'	(b) (4) System	16 Apr 2021 13:18:26

US3462388

Folder: SAE USA-US093-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:40:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:56:40
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:18:26