

US3402381 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:28:24

All time stamps listed in this document are displayed in GMT

US3402381

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

[Participant ID](#)

US3402381

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

US3402381

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 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) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 08 Mar 2021 22:42:46

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Condition	LATEX ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	03 FEB 2009
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)	03 FEB 2009
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2009
Start Year (derived)	2009
Stop Month and Year (derived)	FEB 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Condition	ALLERGY TO GREEN PEPPERS
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Condition	RAW MUSHROOM ALLERGY
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Condition	BEE/WASP ALLERGY
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 (7)

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Condition	CARDIAC STENT PLACEMENT
Start date (dd MMM yyyy)	03 FEB 2009
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)	03 FEB 2009
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2009
Start Year (derived)	2009
Stop Month and Year (derived)	FEB 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Condition	GASTRIC DISTRESS
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN FEB 2009
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)	FEB 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3402381

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:09 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 12:09
Height (<i>xxx.x</i>)	184 cm
Weight (<i>xxx.x</i>)	91 kg
BMI (<i>xxx.x</i>)	26.87854 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) 08 Mar 2021 22:42:46

Generated On: 09 Jun 2021 17:28:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 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) 08 Mar 2021 22:42:46

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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

COMMUNITY ACQUIRED RISK

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Mar 2021 22:42:46

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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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

What was the date of randomization? (dd MMM yyyy) 16 AUG 2020

What was the participant's randomization number? 186500

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) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

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)	16 AUG 2020
Time of assessment (00:00-23:59)	12:09 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 12:09
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

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)	16 AUG 2020
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 13:39
Temperature (xxx.x)	36.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 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) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

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) 16 AUG 2020

What was the treatment time? (00:00-23:59) 13:05 (24 HR)

Treatment Date and Time (derived) 16 AUG 2020 13:05

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	16 AUG 2020
Collection time (<i>00:00-23:59</i>)	12:38 (24 HR)
Collection date and time (derived)	16 AUG 2020 12:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Collection date (dd MMM yyyy)			16 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:35	16 AUG 2020 12:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 13:43

PC Open Date & Time

16 AUG 2020 13:25

PC Close Date & Time

16 AUG 2020 15:55

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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 96.3 °F

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

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

PC Time Stamp	16 AUG 2020 21:18
PC Open Date & Time	16 AUG 2020 16:50
PC Close Date & Time	17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 19:26

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 20:44

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

97.2 °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 AUG 2020 20:53

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

20 AUG 2020 20:42

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 22:46

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 19:39

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

16 AUG 2020 13:44

PC Open Date & Time

16 AUG 2020 13:25

PC Close Date & Time

16 AUG 2020 15:55

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

16 AUG 2020 21:19

PC Open Date & Time

16 AUG 2020 16:50

PC Close Date & Time

17 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

17 AUG 2020 19:27

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

18 AUG 2020 20:45

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

19 AUG 2020 20:54

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

20 AUG 2020 20:43

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

21 AUG 2020 22:47

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

22 AUG 2020 19:40

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

No ☒

Yes ☐

PC Time stamp	16 AUG 2020 13:45
PC Open Date & Time	16 AUG 2020 13:25
PC Close Date & Time	16 AUG 2020 15:55

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

No ☒

Yes ☐

PC Time stamp	16 AUG 2020 21:20
PC Open Date & Time	16 AUG 2020 16:50
PC Close Date & Time	17 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

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 ☒

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 19:28
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2070

EAB) (1725)

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 20:47
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2070

EAB) (1725)

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 20:55
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

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 ☒

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 20:44
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

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 ☒

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 22:48
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2070

EAB) (1725)

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:41
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3402381

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:02
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:16
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3402381

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 11:38 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 11:38

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

US3402381

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 SEP 2020
Collection time (00:00-23:59)	11:24 (24 HR)
Collection date and time (derived)	14 SEP 2020 11:24

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:25	14 SEP 2020 11:25
Nasopharyngeal Swab 2	No		

US3402381

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:17

PC Open Date & Time

14 SEP 2020 11:58

PC Close Date & Time

14 SEP 2020 14:28

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

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

14 SEP 2020 15:23

PC Close Date & Time

15 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 20:17

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 20:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 22:30

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 19:56

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 21:55

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

20 SEP 2020 21:24

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

14 SEP 2020 12:18

PC Open Date & Time

14 SEP 2020 11:58

PC Close Date & Time

14 SEP 2020 14:28

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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 ☐

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.**

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

PC Open Date & Time

14 SEP 2020 15:23

PC Close Date & Time

15 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

15 SEP 2020 20:18

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

16 SEP 2020 20:02

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

17 SEP 2020 22:31

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

18 SEP 2020 19:57

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

19 SEP 2020 21:56

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

20 SEP 2020 21:25

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 12:19
PC Open Date & Time	14 SEP 2020 11:58
PC Close Date & Time	14 SEP 2020 14:28

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 15:23

PC Close Date & Time

15 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

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 ☒

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:18
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

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 ☒

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:03
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

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 ☒

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EAB) (1725)

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 22:32
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

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 ☒

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 19:58
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:54
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

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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US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 21:25
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3402381

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:24:21

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:24:22

Generated On: 09 Jun 2021 17:28:24

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	VISIT3

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 18:24:22

Generated On: 09 Jun 2021 17:28:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:10 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:10
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402381

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:24:22

Generated On: 09 Jun 2021 17:28:24

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.

US3402381

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:24:22

Generated On: 09 Jun 2021 17:28:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 OCT 2020
Collection time (00:00-23:59)	11:18 (24 HR)
Collection date and time (derived)	12 OCT 2020 11:18

US3402381

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:24:22

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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	18 OCT 2020 13:40:44
Patient Cloud Open Date & Time	16 OCT 2020 00:01
Patient Cloud Close Date & Time	20 OCT 2020 23:59

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

26 OCT 2020 00:00:31

Patient Cloud Open Date & Time

23 OCT 2020 00:01

Patient Cloud Close Date & Time

27 OCT 2020 23:59

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 08:15:21
Patient Cloud Open Date & Time	30 OCT 2020 00:01
Patient Cloud Close Date & Time	03 NOV 2020 23:59

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 15:40:24

Patient Cloud Open Date & Time

13 NOV 2020 00:01

Patient Cloud Close Date & Time

17 NOV 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 16:59:13
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 19:33:29

Patient Cloud Open Date & Time

24 NOV 2020 00:01

Patient Cloud Close Date & Time

28 NOV 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	05 DEC 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 10:17:01

Patient Cloud Open Date & Time

08 DEC 2020 00:01

Patient Cloud Close Date & Time

12 DEC 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 08:18:13

Patient Cloud Open Date & Time

15 DEC 2020 00:01

Patient Cloud Close Date & Time

19 DEC 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 19:29:15
Patient Cloud Open Date & Time	22 DEC 2020 00:01
Patient Cloud Close Date & Time	26 DEC 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 19:42:52

Patient Cloud Open Date & Time

29 DEC 2020 00:01

Patient Cloud Close Date & Time

02 JAN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 JAN 2021 13:03:14

Patient Cloud Open Date & Time

05 JAN 2021 00:01

Patient Cloud Close Date & Time

09 JAN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 JAN 2021 17:09:38

Patient Cloud Open Date & Time

12 JAN 2021 00:01

Patient Cloud Close Date & Time

16 JAN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 08:27:15

Patient Cloud Open Date & Time

19 JAN 2021 00:01

Patient Cloud Close Date & Time

23 JAN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 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	27 JAN 2021 14:53:08
Patient Cloud Open Date & Time	26 JAN 2021 00:01
Patient Cloud Close Date & Time	30 JAN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 16:46:40

Patient Cloud Open Date & Time

02 FEB 2021 00:01

Patient Cloud Close Date & Time

06 FEB 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 22:07:09
Patient Cloud Open Date & Time	09 FEB 2021 00:01
Patient Cloud Close Date & Time	13 FEB 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 FEB 2021 17:00:42
Patient Cloud Open Date & Time	16 FEB 2021 00:01
Patient Cloud Close Date & Time	20 FEB 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 FEB 2021 17:52:59
Patient Cloud Open Date & Time	23 FEB 2021 00:01
Patient Cloud Close Date & Time	27 FEB 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 14:12:45

Patient Cloud Open Date & Time

02 MAR 2021 00:01

Patient Cloud Close Date & Time

06 MAR 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 09:42:21

Patient Cloud Open Date & Time

09 MAR 2021 00:01

Patient Cloud Close Date & Time

13 MAR 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 11:43:06

Patient Cloud Open Date & Time

16 MAR 2021 00:01

Patient Cloud Close Date & Time

20 MAR 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

23 MAR 2021 09:04:03

Patient Cloud Open Date & Time

23 MAR 2021 00:01

Patient Cloud Close Date & Time

27 MAR 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 MAR 2021 13:07:47
Patient Cloud Open Date & Time	30 MAR 2021 00:01
Patient Cloud Close Date & Time	03 APR 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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	06 APR 2021 10:42:25
Patient Cloud Open Date & Time	06 APR 2021 00:01
Patient Cloud Close Date & Time	10 APR 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	24 APR 2021 23:59
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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

01 MAY 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAY 2021 00:02:19

Patient Cloud Open Date & Time

04 MAY 2021 00:01

Patient Cloud Close Date & Time

08 MAY 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Open Date & Time](#)

29 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 <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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

10 JUL 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2021 00:01
Patient Cloud Close Date & Time	17 JUL 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	24 JUL 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	14 AUG 2021 23:59
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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 <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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	11 SEP 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

23 OCT 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	11 DEC 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

29 JAN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

05 FEB 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

12 FEB 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

19 FEB 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

26 FEB 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

12 MAR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

19 MAR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 761

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

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

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

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

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

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

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

17 SEP 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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 <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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

08 OCT 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

15 OCT 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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="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"/>

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

[Patient Cloud Close Date & Time](#)

22 OCT 2022 23:59

US3402381

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:28:24

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		02 MAR 2021 14:12:56

US3402381

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:30:06

Generated On: 09 Jun 2021 17:28:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:30:06

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

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

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

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

Visit date (dd MMM yyyy)	15 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	VISIT4
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US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 13:25
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402381

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

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.

US3402381

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 MAR 2021

Collection time (00:00-23:59)

15:05 (24 HR)

Collection date and time (derived)

15 MAR 2021 15:05

US3402381

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402381

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:28:24

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"/>

US3402381

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:28:24

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402381

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

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

Visit date (dd MMM yyyy)	15 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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US3402381

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	15 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

US3402381

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Height	182.9 cm
Weight	91.6 kg
BMI (xxx.x)	27.38218

US3402381

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Height	182.9 cm
Weight	91.6 kg
BMI (xxx.x)	27.38218
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)	15 MAR 2021
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 13:25
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3402381

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Height	182.9 cm
Weight	91.6 kg
BMI (xxx.x)	27.38218
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)	15 MAR 2021
Time of assessment (00:00-23:59)	14:23 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 14:23
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3402381

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

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3402381

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

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 15 MAR 2021

What was the treatment time? (00:00-23:59) 13:52 (24 HR)

Treatment Date and Time (derived) 15 MAR 2021 13:52

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

US3402381

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 MAR 2021

Collection time (00:00-23:59)

15:05 (24 HR)

Collection date and time (derived)

15 MAR 2021 15:05

US3402381

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 MAR 2021

Collection time (00:00 - 23:59)

15:06

Collection Date and Time (derived)

15 MAR 2021 15:06

US3402381

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

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:42:22

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 APR 2021
Time of assessment (<i>00:00-23:59</i>)	13:02 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 13:02
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

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)	9 APR 2021
Time of assessment (00:00-23:59)	13:49 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 13:49
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3402381

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 APR 2021

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

US3402381

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

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) 9 APR 2021

What was the treatment time? (00:00-23:59) 13:17 (24 HR)

Treatment Date and Time (derived) 9 APR 2021 13:17

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402381

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:49:44

Generated On: 09 Jun 2021 17:28:24

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 00:04:58

Generated On: 09 Jun 2021 17:28:24

AEID	USA-US059-2020-MRNA-1273-P30 1000015
Adverse event	PROSTATE CANCER
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)	20 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)	9 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 00:04:58

Generated On: 09 Jun 2021 17:28:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 00:04:58

Generated On: 09 Jun 2021 17:28:24

SUBJECT WAS DIAGNOSED
WITH PROSTATE CANCER
05NOV2020 AFTER HAVING A
BIOPSY 30OCT2020. SUBJECT
BEGAN HAVING SYMPTOMS OF
BLOOD IN SPERM 20SEP2020.
SUBJECT WENT TO UROLOGIST.
AFTER BIOPSY
RESULTSSUBJECT WAS GIVRN
240 MG OF FIRMAGON SUB
CUTANEOUSLY. AND WILL GO
BACK MONTHLY FOR FURTHER
INJECTIONS OF FIRMAGON
80MG. SUBJECT WILL ALSO
BEGIN RADIATION IN
APPROXIMATELY 6 WEEKS.
THIS WAS ENTERED WITH IN 24
HOURS OF SITE AWARENESS

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)	

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

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

Yes ☒

No ☐

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

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

	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 2009	
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) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

	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 2009	
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 (3)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

	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 2009
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 (4)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

	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 2013	
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 (5)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

Name of Medication NAPROSYN (NAPROXEN)

Prophylaxis Yes ☐
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

	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 2009
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 (6)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

Name of Medication PROBIOTIC

Prophylaxis Yes ☐
No ☒

Indication DIGESTIVE DISTRESS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

	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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

Name of Medication FIRMAGON

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 240

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 (7)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

	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)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input checked="" type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

Name of Medication ORGOVYX

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 120

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

	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)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:41:45

Generated On: 09 Jun 2021 17:28:24

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
30 OCT 2020	PROSTATE BIOPSY	Adverse Event	

US3402381

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:28:24

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 ☐

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

SAEID	USA-US059-2020-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

SAEID	USA-US059-2020-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/NOV/2020 11:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

SAEID	USA-US059-2020-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/NOV/2020 16:23
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

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

SAEID	USA-US059-2020-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	20/NOV/2020 17:52
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

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

SAEID	USA-US059-2020-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/NOV/2020 09:44
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

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

SAEID	USA-US059-2020-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/DEC/2020 13:42
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

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 23:35:12

Generated On: 09 Jun 2021 17:28:24

SAEID	USA-US059-2020-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/APR/2021 11:34
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

US3402381 (Prod: Meridian Clinical Research, LLC)

US3402381

Form: Participant Creation

Generated On: 09 Jun 2021 17:28:24

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'US3402381'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:24:10

US3402381

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4)	
	Jennifer Molstead (b) (4)	16 Aug 2020 17:15:29
	(b) (4)	

US3402381

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '16 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:24:11

US3402381

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Clinic (Clinic)'	(b) (4) Jennifer Molstead (b) (4)	16 Aug 2020 17:15:29

US3402381

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'SCRN'	System	16 Aug 2020 17:15:29

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:24:12

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '67'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'YEARS'	System	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '67'	System	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:24

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:24

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '16 Aug 2020'	(b) (4) Jennifer Molstead (b) (4)	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Aug 2020'	System	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '2020'	System	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Amendment 2 (2)'	Jennifer Molstead (b) (4)	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) Jennifer Molstead (b) (4)	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4)	Jennifer Molstead (b) (4) 16 Aug 2020 17:15:40
	(b) (4)	

US3402381

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4)	
	Jennifer Molstead (b) (4)	16 Aug 2020 17:15:40
	(b) (4)	

US3402381

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:24:11

US3402381

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'I'	System	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:28:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:20:51

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Aug 2020 18:22:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 18:22:17
Data point term sent to Coder	System	16 Aug 2020 18:21:15
User entered 'LATEX ALLERGY'	(b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Jan 2000'	System	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '2000'	System	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
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: Chronic back pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 18:23:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 18:23:17
Data point term sent to Coder	System	16 Aug 2020 18:22:18
User entered 'CHRONIC BACK PAIN'	(b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'UN UNK 1989'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Jan 1989'	System	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '1989'	System	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 18:23:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 18:23:17
Data point term sent to Coder	System	16 Aug 2020 18:22:20
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '03 Feb 2009'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '03 Feb 2009'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Feb 2009'	System	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '2009'	System	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Feb 2009'	System	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '2009'	System	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:38:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Food allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 05:22:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 05:22:17
Data point term sent to Coder	System	16 Aug 2020 18:26:21
User entered 'ALLERGY TO GREEN PEPPERS'	(b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'UN UNK 1980'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Jan 1980'	System	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '1980'	System	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Allergy to edible fungus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 19:25:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 19:25:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:42:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Food allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 11:10:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 11:10:57
Data point term sent to Coder	System	16 Aug 2020 19:11:52
User entered 'RAW MUSHROOM ALLERGY'	(b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'UN UNK 1980'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Jan 1980'	System	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '1980'	System	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to arthropod sting, LLT: Allergic reaction to bee sting - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 05:43:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 05:43:25
Data point term sent to Coder	System	16 Aug 2020 19:11:52
User entered 'BEE/WASP ALLERGY'	(b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'UN UNK 1990'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Jan 1990'	System	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '1990'	System	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	16 Aug 2020 19:13:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:13:25
Data point term sent to Coder	System	16 Aug 2020 19:12:52
User entered 'CARDIAC STENT PLACEMENT'	(b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '03 Feb 2009'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '03 Feb 2009'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Feb 2009'	System	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '2009'	System	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Feb 2009'	System	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '2009'	System	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Abdominal discomfort, LLT: Distress gastrointestinal - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 06:53:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 06:53:23
Data point term sent to Coder	System	16 Aug 2020 19:13:54
User entered 'GASTRIC DISTRESS'	(b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'UN UNK 1984'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Jan 1984'	System	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '1984'	System	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 19:15:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 19:15:16
Data point term sent to Coder	(b) (4)	16 Aug 2020 19:13:53
User entered 'CORONARY ARTERY DISEASE'	System (b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'UN Feb 2009'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'Feb 2009'	System	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '2009'	System	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered empty.	System	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '16 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '12:09'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered '16 Aug 2020 12:09'	System	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '184' cm	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:15:09
DataPoint set to visible.	System	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '91' kg	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:15:09
DataPoint set to visible.	System	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
Amendment Manager: User entered '26.87854'	System	16 Sep 2020 23:59:08
User entered '26.9'	System	16 Aug 2020 19:15:09
DataPoint set to visible.	System	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'kg/m2'	System	16 Aug 2020 19:15:09
DataPoint set to visible.	System	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:41
User entered '36.6' C	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:41
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	16 Aug 2020 19:15:09
	(b) (4)	
	(b) (4), (b) (6)	

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:41
User entered '54'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'bpm'	System	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:41
User entered '16'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'breaths/min'	System	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:41
User entered '132'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'mmHg'	System	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:41
User entered '77'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User entered 'mmHg'	System	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53

US3402381

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:15:28

US3402381

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 10:19:11
Comment added 'PLEASE ADVISE ON RESOLUTION AS DATE IS CORRECT'.	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 15:17:37
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 16:10:37
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 19:15:28

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[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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

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[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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

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[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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

Form: Risk of Exposure

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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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'COMMUNITY ACQUIRED RISK'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

Form: Risk of Exposure

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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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

[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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

Form: Risk of Exposure

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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 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:58:53
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:17:01

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:18:11

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:18:11

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:18:11

US3402381

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'VISIT1'	System	16 Aug 2020 19:18:11

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:24:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:24

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:54:15
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:54:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Aug 2020 16:24:13
User entered '186500' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:24:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:24

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:24:13

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Folder: Visit 1 Day 1

Form: Randomization

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Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:18:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:24

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:18:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:24

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:18:31

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Folder: Visit 1 Day 1

Form: Randomization

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[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:18:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:18:31

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Folder: Visit 1 Day 1

Form: Randomization

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Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User closed query 'Per CDM: This field requires yes or no. Please complete' (Site from DM).	(b) (4)	
Query 'Per CDM: This field requires yes or no. Please complete' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:08:03
User entered 'No (N)'	Tammy Kohn (b) (4)	03 Nov 2020 14:57:05
User opened query 'Per CDM: This field requires yes or no. Please complete' (Site from DM).	(b) (4)	
Amendment Manager: DataPoint set to visible.	Tammy Kohn (b) (4)	03 Nov 2020 14:56:59
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	03 Nov 2020 11:33:21
	System	19 Sep 2020 10:22:18
	System	19 Sep 2020 07:33:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:10
User entered '184' cm	Tammy Kohn (b) (4)	16 Aug 2020 19:20:31
	(b) (4)	
	(b) (4), (b) (6)	

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:10
User entered '91' kg	(b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:10
User entered '184' cm	(b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:10
User entered '91' kg	(b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '12:09'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '16 Aug 2020 12:09'	System	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '54'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'bpm'	System	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'breaths/min'	System	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '132'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'mmHg'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '77'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'mmHg'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:10
User entered '184' cm	Tammy Kohn (b) (4)	16 Aug 2020 19:20:31
	(b) (4)	
	(b) (4), (b) (6)	

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 19:28:10
User entered '91' kg	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:29:35
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30MIN' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 19:20:42
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		16 Aug 2020 19:20:31
User entered '13:39'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '16 Aug 2020 13:39'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '36.0' C	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '57'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'bpm'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '14'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'breaths/min'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '117'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'mmHg'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '75'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'mmHg'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:50

US3402381

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:20:50

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4)	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4)	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'MRNA-1273 OR PLACEBO'	System	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16 Aug 2020'	Jennifer Molstead (b) (4)	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '13:05'	Jennifer Molstead (b) (4)	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '16 Aug 2020 13:05'	System	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'ONCE'	System	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'INTRAMUSCULAR'	System	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:21:04

US3402381

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:21:04

US3402381

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '12:38'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:21:04

US3402381

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '16 Aug 2020 12:38'	System	16 Aug 2020 19:21:04

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:28:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '12:35'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '16 Aug 2020 12:35'	System	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered empty.	System	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 19:21:42

US3402381

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'I'	System	16 Aug 2020 19:21:42

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:41:42', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd505f4c9-e908-4cb4-93d9-bf527813a75b'	System	16 Aug 2020 17:43:10
User entered 'Yes (Y)'	System	16 Aug 2020 17:43:10

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:42:26', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd505f4c9-e908-4cb4-93d9-bf527813a75b'	System	16 Aug 2020 17:43:10
User entered '96.9'	System	16 Aug 2020 17:43:10

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:43:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd505f4c9-e908-4cb4-93d9-bf527813a75b'	System	16 Aug 2020 17:43:10
User entered 'No (N)'	System	16 Aug 2020 17:43:10

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:43:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd505f4c9-e908-4cb4-93d9-bf527813a75b'	System	16 Aug 2020 17:43:10
User entered '16 Aug 2020 13:43'	System	16 Aug 2020 17:43:10

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Aug 2020 13:25'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Aug 2020 15:55'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:17:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a41b2cb9-1bd2-4b7c-acae-4adf0e2b4124'	System	17 Aug 2020 01:18:34
User entered 'Yes (Y)'	System	17 Aug 2020 01:18:34

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:17:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a41b2cb9-1bd2-4b7c-acae-4adf0e2b4124'	System	17 Aug 2020 01:18:34
User entered '96.3'	System	17 Aug 2020 01:18:34

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:18:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a41b2cb9-1bd2-4b7c-acae-4adf0e2b4124'	System	17 Aug 2020 01:18:34
User entered 'No (N)'	System	17 Aug 2020 01:18:34

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:18:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a41b2cb9-1bd2-4b7c-acae-4adf0e2b4124'	System	17 Aug 2020 01:18:34
User entered '16 Aug 2020 21:18'	System	17 Aug 2020 01:18:34

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Aug 2020 16:50'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 2'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:25:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b58237cb-dc10-4ea0-8352-bae7d58ef2ce'	System	17 Aug 2020 23:26:56
User entered 'Yes (Y)'	System	17 Aug 2020 23:26:56

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:26:04', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b58237cb-dc10-4ea0-8352-bae7d58ef2ce'	System	17 Aug 2020 23:26:56
User entered '98.1'	System	17 Aug 2020 23:26:56

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:26:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b58237cb-dc10-4ea0-8352-bae7d58ef2ce'	System	17 Aug 2020 23:26:56
User entered 'No (N)'	System	17 Aug 2020 23:26:56

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:26:51', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b58237cb-dc10-4ea0-8352-bae7d58ef2ce'	System	17 Aug 2020 23:26:56
User entered '17 Aug 2020 19:26'	System	17 Aug 2020 23:26:56

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 3'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:44:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b877f79f-74d2-489c-a288-bb5d8779d123'	System	19 Aug 2020 00:44:49
User entered 'Yes (Y)'	System	19 Aug 2020 00:44:49

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:44:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b877f79f-74d2-489c-a288-bb5d8779d123'	System	19 Aug 2020 00:44:49
User entered '97.4'	System	19 Aug 2020 00:44:49

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:44:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b877f79f-74d2-489c-a288-bb5d8779d123'	System	19 Aug 2020 00:44:49
User entered 'No (N)'	System	19 Aug 2020 00:44:49

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:44:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b877f79f-74d2-489c-a288-bb5d8779d123'	System	19 Aug 2020 00:44:49
User entered '18 Aug 2020 20:44'	System	19 Aug 2020 00:44:49

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 4'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7ac94488-7b90-4a1d-800f-608e448d99d3'	System	20 Aug 2020 00:53:37
User entered 'Yes (Y)'	System	20 Aug 2020 00:53:37

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:11', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7ac94488-7b90-4a1d-800f-608e448d99d3'	System	20 Aug 2020 00:53:37
User entered '97.2'	System	20 Aug 2020 00:53:37

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:18', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7ac94488-7b90-4a1d-800f-608e448d99d3'	System	20 Aug 2020 00:53:37
User entered 'No (N)'	System	20 Aug 2020 00:53:37

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7ac94488-7b90-4a1d-800f-608e448d99d3'	System	20 Aug 2020 00:53:37
User entered '19 Aug 2020 20:53'	System	20 Aug 2020 00:53:37

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 5'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:24', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '071290ab-6832-440f-adf7-db0d88415d4c'	System	21 Aug 2020 00:42:48
User entered 'Yes (Y)'	System	21 Aug 2020 00:42:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '071290ab-6832-440f-adf7-db0d88415d4c'	System	21 Aug 2020 00:42:48
User entered '97.2'	System	21 Aug 2020 00:42:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:36', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '071290ab-6832-440f-adf7-db0d88415d4c'	System	21 Aug 2020 00:42:48
User entered 'No (N)'	System	21 Aug 2020 00:42:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '071290ab-6832-440f-adf7-db0d88415d4c'	System	21 Aug 2020 00:42:48
User entered '20 Aug 2020 20:42'	System	21 Aug 2020 00:42:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 6'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:14', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '24b79aed-d136-4b63-a110-dcdddc95b68'	System	22 Aug 2020 02:46:41
User entered 'Yes (Y)'	System	22 Aug 2020 02:46:41

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:25', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '24b79aed-d136-4b63-a110-dcdddc95b68'	System	22 Aug 2020 02:46:41
User entered '96.3'	System	22 Aug 2020 02:46:41

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:30', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '24b79aed-d136-4b63-a110-dcdddc95b68'	System	22 Aug 2020 02:46:41
User entered 'No (N)'	System	22 Aug 2020 02:46:41

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '24b79aed-d136-4b63-a110-dcdddc95b68'	System	22 Aug 2020 02:46:41
User entered '21 Aug 2020 22:46'	System	22 Aug 2020 02:46:41

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 7'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:39:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8d13136a-0a2e-4db2-9888-5dfd69251de9'	System	22 Aug 2020 23:39:48
User entered 'Yes (Y)'	System	22 Aug 2020 23:39:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:39:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8d13136a-0a2e-4db2-9888-5dfd69251de9' User entered '97.1'	System	22 Aug 2020 23:39:48
	System	22 Aug 2020 23:39:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:39:36', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8d13136a-0a2e-4db2-9888-5dfd69251de9'	System	22 Aug 2020 23:39:48
User entered 'No (N)'	System	22 Aug 2020 23:39:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:39:46', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8d13136a-0a2e-4db2-9888-5dfd69251de9'	System	22 Aug 2020 23:39:48
User entered '22 Aug 2020 19:39'	System	22 Aug 2020 23:39:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:43:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3dd521d1-9216-4385-b754-8cf66bd699ee'	System	16 Aug 2020 17:44:40
User entered 'None (1)'	System	16 Aug 2020 17:44:40

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3dd521d1-9216-4385-b754-8cf66bd699ee'	System	16 Aug 2020 17:44:40
User entered 'No (N)'	System	16 Aug 2020 17:44:40

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:17', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3dd521d1-9216-4385-b754-8cf66bd699ee'	System	16 Aug 2020 17:44:40
User entered 'No (N)'	System	16 Aug 2020 17:44:40

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:30', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3dd521d1-9216-4385-b754-8cf66bd699ee'	System	16 Aug 2020 17:44:40
User entered 'None (1)'	System	16 Aug 2020 17:44:40

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3dd521d1-9216-4385-b754-8cf66bd699ee'	System	16 Aug 2020 17:44:40
User entered '16 Aug 2020 13:44'	System	16 Aug 2020 17:44:40

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Aug 2020 13:25'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Aug 2020 15:55'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:18:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1307d122-9840-49c1-a0f3-2f5fccccd82ca'	System	17 Aug 2020 01:19:32
User entered 'None (1)'	System	17 Aug 2020 01:19:32

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:18:57', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1307d122-9840-49c1-a0f3-2f5fcccc82ca'	System	17 Aug 2020 01:19:32
User entered 'No (N)'	System	17 Aug 2020 01:19:32

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1307d122-9840-49c1-a0f3-2f5fccccd82ca'	System	17 Aug 2020 01:19:32
User entered 'No (N)'	System	17 Aug 2020 01:19:32

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:09', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1307d122-9840-49c1-a0f3-2f5fccccd82ca'	System	17 Aug 2020 01:19:32
User entered 'None (1)'	System	17 Aug 2020 01:19:32

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:28', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1307d122-9840-49c1-a0f3-2f5fcccc82ca'	System	17 Aug 2020 01:19:32
User entered '16 Aug 2020 21:19'	System	17 Aug 2020 01:19:32

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Aug 2020 16:50'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 2'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:26:57', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '055d29cf-8d1e-4963-8caf-bce93af58ad0'	System	17 Aug 2020 23:27:42
User entered 'None (1)'	System	17 Aug 2020 23:27:42

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:27:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '055d29cf-8d1e-4963-8caf-bce93af58ad0'	System	17 Aug 2020 23:27:42
User entered 'No (N)'	System	17 Aug 2020 23:27:42

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:27:10', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '055d29cf-8d1e-4963-8caf-bce93af58ad0'	System	17 Aug 2020 23:27:42
User entered 'No (N)'	System	17 Aug 2020 23:27:42

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:27:16', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '055d29cf-8d1e-4963-8caf-bce93af58ad0'	System	17 Aug 2020 23:27:42
User entered 'None (1)'	System	17 Aug 2020 23:27:42

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:27:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '055d29cf-8d1e-4963-8caf-bce93af58ad0'	System	17 Aug 2020 23:27:42
User entered '17 Aug 2020 19:27'	System	17 Aug 2020 23:27:42

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 3'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '862d0ce4-b202-40e5-9b45-dc8bc666a47f'	System	19 Aug 2020 00:45:34
User entered 'None (1)'	System	19 Aug 2020 00:45:34

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '862d0ce4-b202-40e5-9b45-dc8bc666a47f'	System	19 Aug 2020 00:45:34
User entered 'No (N)'	System	19 Aug 2020 00:45:34

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:12', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '862d0ce4-b202-40e5-9b45-dc8bc666a47f'	System	19 Aug 2020 00:45:34
User entered 'No (N)'	System	19 Aug 2020 00:45:34

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:19', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '862d0ce4-b202-40e5-9b45-dc8bc666a47f'	System	19 Aug 2020 00:45:34
User entered 'None (1)'	System	19 Aug 2020 00:45:34

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '862d0ce4-b202-40e5-9b45-dc8bc666a47f'	System	19 Aug 2020 00:45:34
User entered '18 Aug 2020 20:45'	System	19 Aug 2020 00:45:34

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 4'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5695e873-23df-4c4b-8412-64e37d31e0dc'	System	20 Aug 2020 00:54:07
User entered 'None (1)'	System	20 Aug 2020 00:54:07

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:43', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5695e873-23df-4c4b-8412-64e37d31e0dc'	System	20 Aug 2020 00:54:07
User entered 'No (N)'	System	20 Aug 2020 00:54:07

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:53', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5695e873-23df-4c4b-8412-64e37d31e0dc'	System	20 Aug 2020 00:54:07
User entered 'No (N)'	System	20 Aug 2020 00:54:07

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5695e873-23df-4c4b-8412-64e37d31e0dc'	System	20 Aug 2020 00:54:07
User entered 'None (1)'	System	20 Aug 2020 00:54:07

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:04', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5695e873-23df-4c4b-8412-64e37d31e0dc'	System	20 Aug 2020 00:54:07
User entered '19 Aug 2020 20:54'	System	20 Aug 2020 00:54:07

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 5'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7b301dbe-6953-4382-9557-820c86f3cc2a'	System	21 Aug 2020 00:43:21
User entered 'None (1)'	System	21 Aug 2020 00:43:21

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7b301dbe-6953-4382-9557-820c86f3cc2a'	System	21 Aug 2020 00:43:21
User entered 'No (N)'	System	21 Aug 2020 00:43:21

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7b301dbe-6953-4382-9557-820c86f3cc2a'	System	21 Aug 2020 00:43:21
User entered 'No (N)'	System	21 Aug 2020 00:43:21

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7b301dbe-6953-4382-9557-820c86f3cc2a'	System	21 Aug 2020 00:43:21
User entered 'None (1)'	System	21 Aug 2020 00:43:21

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:18', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7b301dbe-6953-4382-9557-820c86f3cc2a'	System	21 Aug 2020 00:43:21
User entered '20 Aug 2020 20:43'	System	21 Aug 2020 00:43:21

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 6'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0c39eb52-5b5f-4287-9c1b-2e2666b409f8'	System	22 Aug 2020 02:47:16
User entered 'None (1)'	System	22 Aug 2020 02:47:16

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0c39eb52-5b5f-4287-9c1b-2e2666b409f8'	System	22 Aug 2020 02:47:16
User entered 'No (N)'	System	22 Aug 2020 02:47:16

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0c39eb52-5b5f-4287-9c1b-2e2666b409f8'	System	22 Aug 2020 02:47:16
User entered 'No (N)'	System	22 Aug 2020 02:47:16

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0c39eb52-5b5f-4287-9c1b-2e2666b409f8'	System	22 Aug 2020 02:47:16
User entered 'None (1)'	System	22 Aug 2020 02:47:16

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:11', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0c39eb52-5b5f-4287-9c1b-2e2666b409f8'	System	22 Aug 2020 02:47:16
User entered '21 Aug 2020 22:47'	System	22 Aug 2020 02:47:16

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 7'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:39:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f62ab1b8-616d-4cc6-a9a6-743abc339535'	System	22 Aug 2020 23:40:20
User entered 'None (1)'	System	22 Aug 2020 23:40:20

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f62ab1b8-616d-4cc6-a9a6-743abc339535'	System	22 Aug 2020 23:40:20
User entered 'No (N)'	System	22 Aug 2020 23:40:20

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f62ab1b8-616d-4cc6-a9a6-743abc339535'	System	22 Aug 2020 23:40:20
User entered 'No (N)'	System	22 Aug 2020 23:40:20

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f62ab1b8-616d-4cc6-a9a6-743abc339535'	System	22 Aug 2020 23:40:20
User entered 'None (1)'	System	22 Aug 2020 23:40:20

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:17', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f62ab1b8-616d-4cc6-a9a6-743abc339535'	System	22 Aug 2020 23:40:20
User entered '22 Aug 2020 19:40'	System	22 Aug 2020 23:40:20

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'None (0)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:51', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'None (0)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364' User entered 'None (0)'	System	16 Aug 2020 17:45:28
	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:45:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364' User entered 'None (0)'	System	16 Aug 2020 17:45:28
	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:45:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'None (0)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:45:10', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'None (0)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:45:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'No (N)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:45:26', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered '16 Aug 2020 13:45'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Aug 2020 13:25'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Aug 2020 15:55'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:48', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:57', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:20:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:20:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'No (N)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:20:26', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered '16 Aug 2020 21:20'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Aug 2020 16:50'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 2'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:27:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'None (0)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'None (0)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:04', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'None (0)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'None (0)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:33', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'None (0)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'No (N)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered '17 Aug 2020 19:28'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 3'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:37', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:47:02', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:47:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:47:27', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:47:35', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'No (N)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:47:57', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered '18 Aug 2020 20:47'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 4'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:14', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:17', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:33', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'No (N)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:55:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered '19 Aug 2020 20:55'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 5'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:25', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:34', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:37', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'No (N)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:44:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered '20 Aug 2020 20:44'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 6'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:22', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:25', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:33', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:54', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:48:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'No (N)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:48:11', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered '21 Aug 2020 22:48'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 7'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:35', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:42', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:46', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'No (N)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:41:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered '22 Aug 2020 19:41'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Aug 2020 20:09:15

US3402381

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '24 Aug 2020'	Jennifer Molstead (b) (4)	24 Aug 2020 20:09:15

US3402381

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	24 Aug 2020 20:09:15

US3402381

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4)	24 Aug 2020 20:09:15

US3402381

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Aug 2020 20:09:27

US3402381

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'I'	System	24 Aug 2020 20:09:27

US3402381

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	01 Sep 2020 21:24:14

US3402381

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '1 Sep 2020'	Traci Hull (b) (4)	01 Sep 2020 21:24:14

US3402381

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	01 Sep 2020 21:24:14

US3402381

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Traci Hull (b) (4)	01 Sep 2020 21:24:14

US3402381

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	01 Sep 2020 21:26:02

US3402381

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'I'	System	01 Sep 2020 21:26:02

US3402381

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	14 Sep 2020 16:10:19

US3402381

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '6 Sep 2020'	Jennifer Molstead (b) (4)	14 Sep 2020 16:10:19

US3402381

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	14 Sep 2020 16:10:19

US3402381

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4)	14 Sep 2020 16:10:19

US3402381

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	14 Sep 2020 16:10:28

US3402381

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'I'	System	14 Sep 2020 16:10:28

US3402381

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	14 Sep 2020 16:10:37

US3402381

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '14 Sep 2020'	Jennifer Molstead (b) (4)	14 Sep 2020 16:10:37

US3402381

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	14 Sep 2020 16:10:37

US3402381

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'VISIT2'	System	14 Sep 2020 16:10:37

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '14 Sep 2020'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '11:02'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '14 Sep 2020 11:02'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '97.9' F	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	(b) (4) Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '56'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'bpm'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16'	(b) (4) Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'breaths/min'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '117'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'mmHg'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '74'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'mmHg'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '14 Sep 2020'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '12:16'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '14 Sep 2020 12:16'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '98.2' F	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	14 Sep 2020 16:35:46
	(b) (4)	

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	14 Sep 2020 16:35:46
	(b) (4)	

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '49'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'bpm'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'breaths/min'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '115'	Traci Hull (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'mmHg'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '73'	(b) (4) Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'mmHg'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	14 Sep 2020 16:35:54

US3402381

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '14 Sep 2020'	Traci Hull (b) (4)	14 Sep 2020 16:35:54

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 16:42:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 16:42:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 16:42:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Sep 2020 16:11:26
User entered empty.	System	14 Sep 2020 16:11:26
	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26
	(b) (4)	

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 16:42:18
User entered empty.	System	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '14 Sep 2020'	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '11:38'	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '14 Sep 2020 11:38'	System	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'ONCE'	System	18 Sep 2020 16:42:18
User entered empty.	System	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 16:42:18
User entered empty.	System	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	14 Sep 2020 16:36:17

US3402381

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '14 Sep 2020'	Traci Hull (b) (4)	14 Sep 2020 16:36:17

US3402381

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '11:24'	(b) (4) Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:17

US3402381

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '14 Sep 2020 11:24'	System	14 Sep 2020 16:36:17

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:28:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '14 Sep 2020'	Traci Hull (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '11:25'	Traci Hull (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '14 Sep 2020 11:25'	System	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	14 Sep 2020 16:36:29
	(b) (4)	

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered empty.	System	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	14 Sep 2020 16:34:00

US3402381

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '1'	System	14 Sep 2020 16:34:00

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:16:51', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a05e5187-d2bf-4539-8ce8-c6b2aa21c611'	System	14 Sep 2020 16:17:21
User entered 'Yes (Y)'	System	14 Sep 2020 16:17:21

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a05e5187-d2bf-4539-8ce8-c6b2aa21c611'	System	14 Sep 2020 16:17:21
User entered '98.2'	System	14 Sep 2020 16:17:21

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a05e5187-d2bf-4539-8ce8-c6b2aa21c611'	System	14 Sep 2020 16:17:21
User entered 'No (N)'	System	14 Sep 2020 16:17:21

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:16', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a05e5187-d2bf-4539-8ce8-c6b2aa21c611'	System	14 Sep 2020 16:17:21
User entered '14 Sep 2020 12:17'	System	14 Sep 2020 16:17:21

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '14 Sep 2020 11:58'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '14 Sep 2020 14:28'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '14 Sep 2020 15:23'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 2'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:04', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b80edac-296d-4ba7-9870-9271c4f6eb23'	System	16 Sep 2020 00:17:31
User entered 'Yes (Y)'	System	16 Sep 2020 00:17:31

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:14', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b80edac-296d-4ba7-9870-9271c4f6eb23'	System	16 Sep 2020 00:17:31
User entered '97.0'	System	16 Sep 2020 00:17:31

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:19', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b80edac-296d-4ba7-9870-9271c4f6eb23'	System	16 Sep 2020 00:17:31
User entered 'No (N)'	System	16 Sep 2020 00:17:31

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b80edac-296d-4ba7-9870-9271c4f6eb23'	System	16 Sep 2020 00:17:31
User entered '15 Sep 2020 20:17'	System	16 Sep 2020 00:17:31

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 3'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:01:30', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '2a72ac71-52ef-45b0-b227-4c64e73c65a9'	System	17 Sep 2020 00:02:01
User entered 'Yes (Y)'	System	17 Sep 2020 00:02:01

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:01:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '2a72ac71-52ef-45b0-b227-4c64e73c65a9'	System	17 Sep 2020 00:02:01
User entered '97.0'	System	17 Sep 2020 00:02:01

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:01:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '2a72ac71-52ef-45b0-b227-4c64e73c65a9'	System	17 Sep 2020 00:02:01
User entered 'No (N)'	System	17 Sep 2020 00:02:01

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:01:54', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '2a72ac71-52ef-45b0-b227-4c64e73c65a9'	System	17 Sep 2020 00:02:01
User entered '16 Sep 2020 20:01'	System	17 Sep 2020 00:02:01

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 4'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:30:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '643ed341-416d-4d25-93e6-d219cc4f985c'	System	18 Sep 2020 02:30:46
User entered 'Yes (Y)'	System	18 Sep 2020 02:30:46

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:30:28', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '643ed341-416d-4d25-93e6-d219cc4f985c' User entered '97.1'	System	18 Sep 2020 02:30:46

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:30:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '643ed341-416d-4d25-93e6-d219cc4f985c'	System	18 Sep 2020 02:30:46
User entered 'No (N)'	System	18 Sep 2020 02:30:46

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:30:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '643ed341-416d-4d25-93e6-d219cc4f985c'	System	18 Sep 2020 02:30:46
User entered '17 Sep 2020 22:30'	System	18 Sep 2020 02:30:46

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 5'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:30', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '271944c2-9e36-4de5-a716-84844c37e684'	System	18 Sep 2020 23:56:55
User entered 'Yes (Y)'	System	18 Sep 2020 23:56:55

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:37', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '271944c2-9e36-4de5-a716-84844c37e684'	System	18 Sep 2020 23:56:55
User entered '97.4'	System	18 Sep 2020 23:56:55

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:42', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '271944c2-9e36-4de5-a716-84844c37e684'	System	18 Sep 2020 23:56:55
User entered 'No (N)'	System	18 Sep 2020 23:56:55

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '271944c2-9e36-4de5-a716-84844c37e684'	System	18 Sep 2020 23:56:55
User entered '18 Sep 2020 19:56'	System	18 Sep 2020 23:56:55

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 6'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:54:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '75d8dae3-ed9e-43e0-a578-4894d7961c1e'	System	20 Sep 2020 01:55:54
User entered 'Yes (Y)'	System	20 Sep 2020 01:55:54

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:55:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '75d8dae3-ed9e-43e0-a578-4894d7961c1e'	System	20 Sep 2020 01:55:54
User entered '96.9'	System	20 Sep 2020 01:55:54

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:55:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '75d8dae3-ed9e-43e0-a578-4894d7961c1e'	System	20 Sep 2020 01:55:54
User entered 'No (N)'	System	20 Sep 2020 01:55:54

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:55:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '75d8dae3-ed9e-43e0-a578-4894d7961c1e'	System	20 Sep 2020 01:55:54
User entered '19 Sep 2020 21:55'	System	20 Sep 2020 01:55:54

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 7'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0e0853a4-0919-476b-a73d-30fb23b75b7a'	System	21 Sep 2020 01:24:39
User entered 'Yes (Y)'	System	21 Sep 2020 01:24:39

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:19', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0e0853a4-0919-476b-a73d-30fb23b75b7a' User entered '97.7'	System	21 Sep 2020 01:24:39
	System	21 Sep 2020 01:24:39

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0e0853a4-0919-476b-a73d-30fb23b75b7a'	System	21 Sep 2020 01:24:39
User entered 'No (N)'	System	21 Sep 2020 01:24:39

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:37', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0e0853a4-0919-476b-a73d-30fb23b75b7a'	System	21 Sep 2020 01:24:39
User entered '20 Sep 2020 21:24'	System	21 Sep 2020 01:24:39

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9719b86d-a775-4f6a-a08b-9211a706becc'	System	14 Sep 2020 16:18:19
User entered 'None (1)'	System	14 Sep 2020 16:18:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9719b86d-a775-4f6a-a08b-9211a706becc'	System	14 Sep 2020 16:18:19
User entered 'No (N)'	System	14 Sep 2020 16:18:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:59', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9719b86d-a775-4f6a-a08b-9211a706becc'	System	14 Sep 2020 16:18:19
User entered 'No (N)'	System	14 Sep 2020 16:18:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9719b86d-a775-4f6a-a08b-9211a706becc'	System	14 Sep 2020 16:18:19
User entered 'None (1)'	System	14 Sep 2020 16:18:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:16', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9719b86d-a775-4f6a-a08b-9211a706becc'	System	14 Sep 2020 16:18:19
User entered '14 Sep 2020 12:18'	System	14 Sep 2020 16:18:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '14 Sep 2020 11:58'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '14 Sep 2020 14:28'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '14 Sep 2020 15:23'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 2'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:36', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '91fa9c40-8ea5-452d-93ea-c3d4f41ccf15'	System	16 Sep 2020 00:18:10
User entered 'None (1)'	System	16 Sep 2020 00:18:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '91fa9c40-8ea5-452d-93ea-c3d4f41ccf15'	System	16 Sep 2020 00:18:10
User entered 'No (N)'	System	16 Sep 2020 00:18:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '91fa9c40-8ea5-452d-93ea-c3d4f41ccf15'	System	16 Sep 2020 00:18:10
User entered 'No (N)'	System	16 Sep 2020 00:18:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '91fa9c40-8ea5-452d-93ea-c3d4f41ccf15'	System	16 Sep 2020 00:18:10
User entered 'None (1)'	System	16 Sep 2020 00:18:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '91fa9c40-8ea5-452d-93ea-c3d4f41ccf15'	System	16 Sep 2020 00:18:10
User entered '15 Sep 2020 20:18'	System	16 Sep 2020 00:18:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 3'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b8fa8048-8190-459b-a13e-5ddf4c55c28c'	System	17 Sep 2020 00:02:39
User entered 'None (1)'	System	17 Sep 2020 00:02:39

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:09', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b8fa8048-8190-459b-a13e-5ddf4c55c28c'	System	17 Sep 2020 00:02:39
User entered 'No (N)'	System	17 Sep 2020 00:02:39

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:14', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b8fa8048-8190-459b-a13e-5ddf4c55c28c'	System	17 Sep 2020 00:02:39
User entered 'No (N)'	System	17 Sep 2020 00:02:39

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b8fa8048-8190-459b-a13e-5ddf4c55c28c'	System	17 Sep 2020 00:02:39
User entered 'None (1)'	System	17 Sep 2020 00:02:39

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b8fa8048-8190-459b-a13e-5ddf4c55c28c'	System	17 Sep 2020 00:02:39
User entered '16 Sep 2020 20:02'	System	17 Sep 2020 00:02:39

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 4'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:30:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '30ba2a8d-5d48-4e40-9ac3-0fb698df41df'	System	18 Sep 2020 02:31:33
User entered 'None (1)'	System	18 Sep 2020 02:31:33

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:06', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '30ba2a8d-5d48-4e40-9ac3-0fb698df41df'	System	18 Sep 2020 02:31:33
User entered 'No (N)'	System	18 Sep 2020 02:31:33

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:12', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '30ba2a8d-5d48-4e40-9ac3-0fb698df41df'	System	18 Sep 2020 02:31:33
User entered 'No (N)'	System	18 Sep 2020 02:31:33

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:19', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '30ba2a8d-5d48-4e40-9ac3-0fb698df41df'	System	18 Sep 2020 02:31:33
User entered 'None (1)'	System	18 Sep 2020 02:31:33

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:27', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '30ba2a8d-5d48-4e40-9ac3-0fb698df41df'	System	18 Sep 2020 02:31:33
User entered '17 Sep 2020 22:31'	System	18 Sep 2020 02:31:33

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 5'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'ce6f13c1-9423-4cdf-907d-f8c83def1427'	System	18 Sep 2020 23:57:25
User entered 'None (1)'	System	18 Sep 2020 23:57:25

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'ce6f13c1-9423-4cdf-907d-f8c83def1427'	System	18 Sep 2020 23:57:25
User entered 'No (N)'	System	18 Sep 2020 23:57:25

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:02', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'ce6f13c1-9423-4cdf-907d-f8c83def1427'	System	18 Sep 2020 23:57:25
User entered 'No (N)'	System	18 Sep 2020 23:57:25

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'ce6f13c1-9423-4cdf-907d-f8c83def1427'	System	18 Sep 2020 23:57:25
User entered 'None (1)'	System	18 Sep 2020 23:57:25

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'ce6f13c1-9423-4cdf-907d-f8c83def1427'	System	18 Sep 2020 23:57:25
User entered '18 Sep 2020 19:57'	System	18 Sep 2020 23:57:25

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 6'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:55:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7bc7cf26-0b56-4347-8a19-fa8b8040ca44'	System	20 Sep 2020 01:56:19
User entered 'None (1)'	System	20 Sep 2020 01:56:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:55:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7bc7cf26-0b56-4347-8a19-fa8b8040ca44'	System	20 Sep 2020 01:56:19
User entered 'No (N)'	System	20 Sep 2020 01:56:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:56:02', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7bc7cf26-0b56-4347-8a19-fa8b8040ca44'	System	20 Sep 2020 01:56:19
User entered 'No (N)'	System	20 Sep 2020 01:56:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:56:09', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7bc7cf26-0b56-4347-8a19-fa8b8040ca44'	System	20 Sep 2020 01:56:19
User entered 'None (1)'	System	20 Sep 2020 01:56:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:56:16', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7bc7cf26-0b56-4347-8a19-fa8b8040ca44'	System	20 Sep 2020 01:56:19
User entered '19 Sep 2020 21:56'	System	20 Sep 2020 01:56:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 7'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:42', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3ab3671a-da86-49f7-80c5-699f4336161f'	System	21 Sep 2020 01:25:10
User entered 'None (1)'	System	21 Sep 2020 01:25:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3ab3671a-da86-49f7-80c5-699f4336161f'	System	21 Sep 2020 01:25:10
User entered 'No (N)'	System	21 Sep 2020 01:25:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:53', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3ab3671a-da86-49f7-80c5-699f4336161f'	System	21 Sep 2020 01:25:10
User entered 'No (N)'	System	21 Sep 2020 01:25:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3ab3671a-da86-49f7-80c5-699f4336161f'	System	21 Sep 2020 01:25:10
User entered 'None (1)'	System	21 Sep 2020 01:25:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:06', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3ab3671a-da86-49f7-80c5-699f4336161f'	System	21 Sep 2020 01:25:10
User entered '20 Sep 2020 21:25'	System	21 Sep 2020 01:25:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:25', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:19:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'No (N)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:19:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered '14 Sep 2020 12:19'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '14 Sep 2020 11:58'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '14 Sep 2020 14:28'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '14 Sep 2020 15:23'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 2'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:15', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:20', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:35', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'No (N)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:59', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered '15 Sep 2020 20:18'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 3'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:43', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:46', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:53', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:03:02', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'No (N)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:03:17', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered '16 Sep 2020 20:03'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 4'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:36', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:32:13', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:32:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:32:28', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'No (N)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:32:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered '17 Sep 2020 22:32'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 5'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:28', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:34', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e' User entered 'None (0)'	System	18 Sep 2020 23:58:03
	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:51', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'No (N)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:58:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered '18 Sep 2020 19:58'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 6'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:53:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered 'None (0)'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:53:48', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d' User entered 'None (0)'	System	20 Sep 2020 01:54:27
	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:53:54', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered 'None (0)'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:53:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d' User entered 'None (0)'	System	20 Sep 2020 01:54:27
	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:54:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d' User entered 'None (0)'	System	20 Sep 2020 01:54:27
	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:54:04', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d' User entered 'None (0)'	System	20 Sep 2020 01:54:27
	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:54:12', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered 'No (N)'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:54:24', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered '19 Sep 2020 21:54'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 7'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:13', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:18', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:30', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:34', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:37', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'No (N)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered '20 Sep 2020 21:25'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:47:32

US3402381

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '21 Sep 2020'	Traci Hull (b) (4)	21 Sep 2020 20:47:32

US3402381

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	21 Sep 2020 20:47:32

US3402381

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Traci Hull (b) (4)	21 Sep 2020 20:47:32

US3402381

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	21 Sep 2020 20:47:23

US3402381

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'I'	System	21 Sep 2020 20:47:23

US3402381

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4)	29 Sep 2020 20:22:25
	Traci Hull (b) (4)	
	(b) (4)	

US3402381

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '28 Sep 2020'	Traci Hull (b) (4)	29 Sep 2020 20:22:25

US3402381

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	29 Sep 2020 20:22:25

US3402381

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	29 Sep 2020 20:22:25
	(b) (4)	

US3402381

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	29 Sep 2020 20:22:29

US3402381

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'I'	System	29 Sep 2020 20:22:29

US3402381

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	07 Oct 2020 13:29:20

US3402381

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '5 Oct 2020'	Tammy Kohn (b) (4)	07 Oct 2020 13:29:20

US3402381

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	07 Oct 2020 13:29:20

US3402381

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Tammy Kohn (b) (4)	07 Oct 2020 13:29:20

US3402381

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	07 Oct 2020 13:29:24

US3402381

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'I'	System	07 Oct 2020 13:29:24

US3402381

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	12 Oct 2020 16:15:37
	(b) (4)	

US3402381

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '12 Oct 2020'	(b) (4)	
	Traci Hull (b) (4)	12 Oct 2020 16:15:37
	(b) (4)	

US3402381

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	12 Oct 2020 16:15:37

US3402381

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'VISIT3'	System	12 Oct 2020 16:15:37

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '12 Oct 2020'	(b) (4)	
	Traci Hull (b) (4)	12 Oct 2020 16:16:07
	(b) (4)	

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '11:10'	Traci Hull (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '12 Oct 2020 11:10'	System	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '36.8' C	(b) (4)	
	Traci Hull (b) (4)	12 Oct 2020 16:16:07
	(b) (4)	

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	12 Oct 2020 16:16:07
	(b) (4)	

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '66'	Traci Hull (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'bpm'	System	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '16'	Traci Hull (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'breaths/min'	System	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '126'	Traci Hull (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'mmHg'	System	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '78'	Traci Hull (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'mmHg'	System	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'No (N)'	(b) (4)	12 Oct 2020 16:16:16
	Traci Hull (b) (4)	
	(b) (4)	

US3402381

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Traci Hull (b) (4)	12 Oct 2020 16:16:16

US3402381

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	12 Oct 2020 16:16:32

US3402381

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '12 Oct 2020'	Traci Hull (b) (4)	12 Oct 2020 16:16:32

US3402381

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered '11:18'	Traci Hull (b) (4)	12 Oct 2020 16:16:32

US3402381

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered '12 Oct 2020 11:18'	System	12 Oct 2020 16:16:32

US3402381

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	12 Oct 2020 16:15:28

US3402381

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'I'	System	12 Oct 2020 16:15:28

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 64'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-18T13:40:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '22ffa12e-0868-42d8-92ff-0782eba09f13'	System	18 Oct 2020 17:40:48
User entered 'No (N)'	System	18 Oct 2020 17:40:48

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-18T13:40:36', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '22ffa12e-0868-42d8-92ff-0782eba09f13'	System	18 Oct 2020 17:40:48
User entered 'No (N)'	System	18 Oct 2020 17:40:48

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-18T13:40:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '22ffa12e-0868-42d8-92ff-0782eba09f13'	System	18 Oct 2020 17:40:48
User entered '18 Oct 2020 13:40:44'	System	18 Oct 2020 17:40:48

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '16 Oct 2020 00:01'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '20 Oct 2020 23:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 71'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-25T23:59:59', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '60cbe9d3-7a27-4d0e-a6d7-dccc8ffb963e'	System	26 Oct 2020 04:00:34
User entered 'No (N)'	System	26 Oct 2020 04:00:34

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-26T00:00:09', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '60cbe9d3-7a27-4d0e-a6d7-dccc8ffb963e'	System	26 Oct 2020 04:00:34
User entered 'No (N)'	System	26 Oct 2020 04:00:34

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-26T00:00:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '60cbe9d3-7a27-4d0e-a6d7-dccc8ffb963e' User entered '26 Oct 2020 00:00:31'	System	26 Oct 2020 04:00:34
	System	26 Oct 2020 04:00:34

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '23 Oct 2020 00:01'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '27 Oct 2020 23:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 78'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-03T08:15:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6b978ab9-b7ac-4a89-bfe7-95b8431ac11a'	System	03 Nov 2020 13:15:27
User entered 'No (N)'	System	03 Nov 2020 13:15:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-03T08:14:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6b978ab9-b7ac-4a89-bfe7-95b8431ac11a'	System	03 Nov 2020 13:15:27
User entered 'No (N)'	System	03 Nov 2020 13:15:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-03T08:15:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6b978ab9-b7ac-4a89-bfe7-95b8431ac11a'	System	03 Nov 2020 13:15:27
User entered '03 Nov 2020 08:15:21'	System	03 Nov 2020 13:15:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '30 Oct 2020 00:01'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '03 Nov 2020 23:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 92'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-17T15:40:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e3a1c205-f965-4c2b-9869-4f43fc029462'	System	17 Nov 2020 20:40:27
User entered 'No (N)'	System	17 Nov 2020 20:40:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-17T15:40:11', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e3a1c205-f965-4c2b-9869-4f43fc029462'	System	17 Nov 2020 20:40:27
User entered 'No (N)'	System	17 Nov 2020 20:40:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-17T15:40:24', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e3a1c205-f965-4c2b-9869-4f43fc029462'	System	17 Nov 2020 20:40:27
User entered '17 Nov 2020 15:40:24'	System	17 Nov 2020 20:40:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '13 Nov 2020 00:01'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:48:45
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '17 Nov 2020 23:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2020-11-21T16:58:51', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '36b2ee8e-1097-4520-9ddd-5c78e2891d0f'	System	21 Nov 2020 21:59:16
User entered 'No (N)'	System	21 Nov 2020 21:59:16

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2020-11-21T16:58:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '36b2ee8e-1097-4520-9ddd-5c78e2891d0f'	System	21 Nov 2020 21:59:16
User entered 'No (N)'	System	21 Nov 2020 21:59:16

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-21T16:59:13', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '36b2ee8e-1097-4520-9ddd-5c78e2891d0f'	System	21 Nov 2020 21:59:16
User entered '21 Nov 2020 16:59:13'	System	21 Nov 2020 21:59:16

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2020-11-27T19:33:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '01f29db4-d071-4767-8a36-8b7ba1053a75'	System	28 Nov 2020 00:33:34
User entered 'No (N)'	System	28 Nov 2020 00:33:34

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2020-11-27T19:33:19', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '01f29db4-d071-4767-8a36-8b7ba1053a75'	System	28 Nov 2020 00:33:34
User entered 'No (N)'	System	28 Nov 2020 00:33:34

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-27T19:33:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '01f29db4-d071-4767-8a36-8b7ba1053a75'	System	28 Nov 2020 00:33:34
User entered '27 Nov 2020 19:33:29'	System	28 Nov 2020 00:33:34

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2020-12-11T10:16:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '985ac9af-02f0-4472-97ba-a49597c53ae8'	System	11 Dec 2020 15:17:03
User entered 'No (N)'	System	11 Dec 2020 15:17:03

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2020-12-11T10:16:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '985ac9af-02f0-4472-97ba-a49597c53ae8'	System	11 Dec 2020 15:17:03
User entered 'No (N)'	System	11 Dec 2020 15:17:03

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-12-11T10:17:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '985ac9af-02f0-4472-97ba-a49597c53ae8' User entered '11 Dec 2020 10:17:01'	System	11 Dec 2020 15:17:03
	System	11 Dec 2020 15:17:03

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2020-12-15T08:17:57', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '64d0beed-c992-4556-823b-c97f9bde1757'	System	15 Dec 2020 13:18:17
User entered 'No (N)'	System	15 Dec 2020 13:18:17

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2020-12-15T08:18:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '64d0beed-c992-4556-823b-c97f9bde1757'	System	15 Dec 2020 13:18:17
User entered 'No (N)'	System	15 Dec 2020 13:18:17

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-12-15T08:18:13', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '64d0beed-c992-4556-823b-c97f9bde1757'	System	15 Dec 2020 13:18:17
User entered '15 Dec 2020 08:18:13'	System	15 Dec 2020 13:18:17

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2020-12-23T19:29:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '086e0231-2760-4a0e-a6b3-e1690cbc0077'	System	24 Dec 2020 00:29:19
User entered 'No (N)'	System	24 Dec 2020 00:29:19

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2020-12-23T19:29:09', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '086e0231-2760-4a0e-a6b3-e1690cbc0077'	System	24 Dec 2020 00:29:19
User entered 'No (N)'	System	24 Dec 2020 00:29:19

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-12-23T19:29:15', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '086e0231-2760-4a0e-a6b3-e1690cbc0077'	System	24 Dec 2020 00:29:19
User entered '23 Dec 2020 19:29:15'	System	24 Dec 2020 00:29:19

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2020-12-29T19:42:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3782feb8-ac2e-4356-b950-60cba271a2b8'	System	30 Dec 2020 00:42:58
User entered 'No (N)'	System	30 Dec 2020 00:42:58

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2020-12-29T19:42:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3782feb8-ac2e-4356-b950-60cba271a2b8'	System	30 Dec 2020 00:42:58
User entered 'No (N)'	System	30 Dec 2020 00:42:58

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-12-29T19:42:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3782feb8-ac2e-4356-b950-60cba271a2b8' User entered '29 Dec 2020 19:42:52'	System	30 Dec 2020 00:42:58

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-01-05T13:03:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3d6c901f-5125-4512-8bed-9885696d676e'	System	05 Jan 2021 18:03:18
User entered 'No (N)'	System	05 Jan 2021 18:03:18

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-01-05T13:03:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3d6c901f-5125-4512-8bed-9885696d676e'	System	05 Jan 2021 18:03:18
User entered 'No (N)'	System	05 Jan 2021 18:03:18

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-01-05T13:03:14', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3d6c901f-5125-4512-8bed-9885696d676e'	System	05 Jan 2021 18:03:18
User entered '05 Jan 2021 13:03:14'	System	05 Jan 2021 18:03:18

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-01-12T17:09:28', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '74318ac8-0323-444a-bdc7-1addb4c62704'	System	12 Jan 2021 22:09:42
User entered 'No (N)'	System	12 Jan 2021 22:09:42

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-01-12T17:09:33', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '74318ac8-0323-444a-bdc7-1addb4c62704'	System	12 Jan 2021 22:09:42
User entered 'No (N)'	System	12 Jan 2021 22:09:42

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-01-12T17:09:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '74318ac8-0323-444a-bdc7-1addb4c62704'	System	12 Jan 2021 22:09:42
User entered '12 Jan 2021 17:09:38'	System	12 Jan 2021 22:09:42

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-01-19T08:26:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'de231d51-c5ba-4e37-aa37-0df93616fd3c'	System	19 Jan 2021 13:27:20
User entered 'No (N)'	System	19 Jan 2021 13:27:20

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-01-19T08:27:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'de231d51-c5ba-4e37-aa37-0df93616fd3c'	System	19 Jan 2021 13:27:20
User entered 'No (N)'	System	19 Jan 2021 13:27:20

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-01-19T08:27:15', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'de231d51-c5ba-4e37-aa37-0df93616fd3c'	System	19 Jan 2021 13:27:20
User entered '19 Jan 2021 08:27:15'	System	19 Jan 2021 13:27:20

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-01-27T14:52:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e3393c1c-27e0-482a-b44d-c747bf4438a4'	System	27 Jan 2021 19:53:11
User entered 'No (N)'	System	27 Jan 2021 19:53:11

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-01-27T14:53:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e3393c1c-27e0-482a-b44d-c747bf4438a4'	System	27 Jan 2021 19:53:11
User entered 'No (N)'	System	27 Jan 2021 19:53:11

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-01-27T14:53:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e3393c1c-27e0-482a-b44d-c747bf4438a4'	System	27 Jan 2021 19:53:11
User entered '27 Jan 2021 14:53:08'	System	27 Jan 2021 19:53:11

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-02-02T16:46:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0312d0b6-26a3-42f9-a76f-6cd315fe7935'	System	02 Feb 2021 21:46:43
User entered 'No (N)'	System	02 Feb 2021 21:46:43

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-02-02T16:46:35', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0312d0b6-26a3-42f9-a76f-6cd315fe7935'	System	02 Feb 2021 21:46:43
User entered 'No (N)'	System	02 Feb 2021 21:46:43

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-02-02T16:46:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0312d0b6-26a3-42f9-a76f-6cd315fe7935'	System	02 Feb 2021 21:46:43
User entered '02 Feb 2021 16:46:40'	System	02 Feb 2021 21:46:43

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-02-10T22:06:42', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'fd1ea08d-5369-4fbb-a055-aeacb8880cef'	System	11 Feb 2021 03:09:41
User entered 'No (N)'	System	11 Feb 2021 03:09:41

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-02-10T22:06:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'fd1ea08d-5369-4fbb-a055-aeacb8880cef'	System	11 Feb 2021 03:09:41
User entered 'No (N)'	System	11 Feb 2021 03:09:41

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-02-10T22:07:09', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'fd1ea08d-5369-4fbb-a055-aeacb8880cef' User entered '10 Feb 2021 22:07:09'	System	11 Feb 2021 03:09:41
	System	11 Feb 2021 03:09:41

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-02-17T16:59:11', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd099b36a-1a69-4cc7-8c70-0bd271d91895'	System	17 Feb 2021 22:00:48
User entered 'Yes (Y)'	System	17 Feb 2021 22:00:48

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-02-17T16:59:16', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd099b36a-1a69-4cc7-8c70-0bd271d91895'	System	17 Feb 2021 22:00:48
User entered 'No (N)'	System	17 Feb 2021 22:00:48

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-02-17T16:59:22', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd099b36a-1a69-4cc7-8c70-0bd271d91895'	System	17 Feb 2021 22:00:48
User entered 'No (N)'	System	17 Feb 2021 22:00:48

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-02-17T17:00:02', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd099b36a-1a69-4cc7-8c70-0bd271d91895'	System	17 Feb 2021 22:00:48
User entered 'No (N)'	System	17 Feb 2021 22:00:48

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-02-17T17:00:42', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd099b36a-1a69-4cc7-8c70-0bd271d91895'	System	17 Feb 2021 22:00:48
User entered '17 Feb 2021 17:00:42'	System	17 Feb 2021 22:00:48

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-02-23T17:52:41-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6c099d7f-7d5a-4b46-9570-56dc7c73c51a'	System	23 Feb 2021 22:53:03
User entered 'No (N)'	System	23 Feb 2021 22:53:03

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-02-23T17:52:47-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6c099d7f-7d5a-4b46-9570-56dc7c73c51a'	System	23 Feb 2021 22:53:03
User entered 'No (N)'	System	23 Feb 2021 22:53:03

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-02-23T17:52:59-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6c099d7f-7d5a-4b46-9570-56dc7c73c51a'	System	23 Feb 2021 22:53:03
User entered '23 Feb 2021 17:52:59'	System	23 Feb 2021 22:53:03

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-03-02T14:12:24-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e29e7ef2-4187-456c-b89e-609a3200c377'	System	02 Mar 2021 19:12:48
User entered 'No (N)'	System	02 Mar 2021 19:12:48

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-03-02T14:12:30-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e29e7ef2-4187-456c-b89e-609a3200c377'	System	02 Mar 2021 19:12:48
User entered 'No (N)'	System	02 Mar 2021 19:12:48

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-03-02T14:12:45-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e29e7ef2-4187-456c-b89e-609a3200c377'	System	02 Mar 2021 19:12:48
User entered '02 Mar 2021 14:12:45'	System	02 Mar 2021 19:12:48

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-03-11T09:42:10-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'aa877860-ca92-4089-ada6-577878832f88'	System	16 Mar 2021 15:42:14
User entered 'No (N)'	System	16 Mar 2021 15:42:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-03-11T09:42:14-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'aa877860-ca92-4089-ada6-577878832f88'	System	16 Mar 2021 15:42:14
User entered 'No (N)'	System	16 Mar 2021 15:42:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-03-11T09:42:21-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'aa877860-ca92-4089-ada6-577878832f88' User entered '11 Mar 2021 09:42:21'	System	16 Mar 2021 15:42:14
	System	16 Mar 2021 15:42:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-03-16T11:42:44-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '65f35d6c-f3a7-47a7-a2a7-257be79fb64c'	System	16 Mar 2021 15:43:11
User entered 'No (N)'	System	16 Mar 2021 15:43:11

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-03-16T11:42:51-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '65f35d6c-f3a7-47a7-a2a7-257be79fb64c'	System	16 Mar 2021 15:43:11
User entered 'No (N)'	System	16 Mar 2021 15:43:11

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-03-16T11:43:06-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '65f35d6c-f3a7-47a7-a2a7-257be79fb64c'	System	16 Mar 2021 15:43:11
User entered '16 Mar 2021 11:43:06'	System	16 Mar 2021 15:43:11

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-03-23T09:03:54-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '908a070e-c77a-4484-b3f1-d1790250828c'	System	23 Mar 2021 13:04:08
User entered 'No (N)'	System	23 Mar 2021 13:04:08

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-03-23T09:03:58-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '908a070e-c77a-4484-b3f1-d1790250828c'	System	23 Mar 2021 13:04:08
User entered 'No (N)'	System	23 Mar 2021 13:04:08

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-03-23T09:04:03-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '908a070e-c77a-4484-b3f1-d1790250828c' User entered '23 Mar 2021 09:04:03'	System	23 Mar 2021 13:04:08
	System	23 Mar 2021 13:04:08

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-03-30T13:07:39-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '659be6fe-b61d-4137-bccf-1308f17e260e'	System	30 Mar 2021 17:10:37
User entered 'No (N)'	System	30 Mar 2021 17:10:37

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-03-30T13:07:42-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '659be6fe-b61d-4137-bccf-1308f17e260e'	System	30 Mar 2021 17:10:37
User entered 'No (N)'	System	30 Mar 2021 17:10:37

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-03-30T13:07:47-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '659be6fe-b61d-4137-bccf-1308f17e260e' User entered '30 Mar 2021 13:07:47'	System	30 Mar 2021 17:10:37
	System	30 Mar 2021 17:10:37

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-04-06T10:42:15-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'fb8b7a6d-eae0-4d62-b006-282410b7d1bc'	System	06 Apr 2021 14:42:29
User entered 'No (N)'	System	06 Apr 2021 14:42:29

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-04-06T10:42:20-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'fb8b7a6d-eae0-4d62-b006-282410b7d1bc'	System	06 Apr 2021 14:42:29
User entered 'No (N)'	System	06 Apr 2021 14:42:29

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-04-06T10:42:25-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'fb8b7a6d-eae0-4d62-b006-282410b7d1bc'	System	06 Apr 2021 14:42:29
User entered '06 Apr 2021 10:42:25'	System	06 Apr 2021 14:42:29

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[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 (e9fe2538b25b1bad)', Time: '2021-05-04T00:02:02-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '567246f6-2e1d-4c0d-be7e-c203286adbab'	System	04 May 2021 04:04:25
User entered 'No (N)'	System	04 May 2021 04:04:25

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

Have you been exposed to someone with 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 (e9fe2538b25b1bad)', Time: '2021-05-04T00:02:07-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '567246f6-2e1d-4c0d-be7e-c203286adbab'	System	04 May 2021 04:04:25
User entered 'No (N)'	System	04 May 2021 04:04:25

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-05-04T00:02:19-04:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '567246f6-2e1d-4c0d-be7e-c203286adbab'	System	04 May 2021 04:04:25
User entered '04 May 2021 00:02:19'	System	04 May 2021 04:04:25

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 Oct 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Oct 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 Oct 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Oct 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:28:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-03-02T14:12:52-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd7973777-cab0-4d92-ac10-31dfd6996fe4'	System	02 Mar 2021 19:12:59
User entered 'No (N)'	System	02 Mar 2021 19:12:59

US3402381

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:28:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:11:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2021-03-02T14:12:56-05:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd7973777-cab0-4d92-ac10-31dfd6996fe4'	System	02 Mar 2021 19:12:59
User entered '02 Mar 2021 14:12:56'	System	02 Mar 2021 19:12:59

US3402381

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:30:06
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:22

US3402381

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:30:06
User entered '09 Nov 2020'	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:22

US3402381

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:30:06
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:22

US3402381

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:30:06
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:22

US3402381

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:30:06
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:28

US3402381

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:02:07
User entered 'I'	System	09 Nov 2020 15:31:28

US3402381

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:51:01

US3402381

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered '11 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 20:51:01

US3402381

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Dec 2020 20:51:01

US3402381

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:51:01

US3402381

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:51:05

US3402381

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User entered 'I'	System	14 Dec 2020 20:51:05

US3402381

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	11 Jan 2021 20:50:59
	(b) (4)	

US3402381

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered '11 Jan 2021'	Tammy Kohn (b) (4)	11 Jan 2021 20:50:59
	(b) (4)	

US3402381

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	11 Jan 2021 20:50:59
	(b) (4)	

US3402381

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	11 Jan 2021 20:50:59
	(b) (4)	

US3402381

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	11 Jan 2021 20:51:05
	(b) (4)	

US3402381

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User entered 'I'	System	11 Jan 2021 20:51:05

US3402381

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:22
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:28:48

US3402381

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered '8 Feb 2021'	Traci Hull (b) (4)	09 Feb 2021 13:28:48
	(b) (4)	

US3402381

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:22
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:28:48

US3402381

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	09 Feb 2021 13:28:48
	(b) (4)	

US3402381

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Feb 2021 13:28:52
	(b) (4)	

US3402381

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:45:36
User entered 'I'	System	09 Feb 2021 13:28:52

US3402381

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:25:54

US3402381

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:25:54
	(b) (4)	

US3402381

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered 'Clinic (Clinic)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:25:54

US3402381

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User entered 'VISIT4'	System	16 Mar 2021 12:25:54

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 12:39:56
	(b) (4)	

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '13:25'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User entered '15 Mar 2021 13:25'	System	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '36.1' C	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 12:39:56
	(b) (4)	

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '70'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User entered 'bpm'	System	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '16'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User entered 'breaths/min'	System	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '118'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User entered 'mmHg'	System	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '70'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User entered 'mmHg'	System	31 Mar 2021 12:39:56

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13

US3402381

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13

US3402381

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:25:59

US3402381

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:25:59

US3402381

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:26:28

US3402381

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:26:28
	(b) (4)	

US3402381

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '15:05'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:26:28

US3402381

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User entered '15 Mar 2021 15:05'	System	16 Mar 2021 12:26:28

US3402381

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:26:31

US3402381

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:59:13
User entered 'I'	System	16 Mar 2021 12:26:31

US3402381

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

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	15 Mar 2021 20:28:01

US3402381

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

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	15 Mar 2021 20:28:01
	(b) (4)	

US3402381

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

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Clinic (Clinic)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	15 Mar 2021 20:28:01

US3402381

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

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'UNBLND_DECIDE'	System	15 Mar 2021 20:28:01

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '06 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	15 Mar 2021 20:28:30

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '0'	(b) (4) Tammy Kohn (b) (4)	15 Mar 2021 20:28:30

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	15 Mar 2021 20:28:30

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Amendment 6 or later (Amendment 6 or later)'	Tammy Kohn (b) (4)	15 Mar 2021 20:28:30

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	15 Mar 2021 20:28:30
	(b) (4)	

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Placebo (Placebo)'	(b) (4) Tammy Kohn (b) (4)	15 Mar 2021 20:28:30

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Placebo (Placebo)'	Tammy Kohn (b) (4)	15 Mar 2021 20:28:30

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Placebo (Placebo)'	Tammy Kohn (b) (4)	15 Mar 2021 20:28:30

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	15 Mar 2021 20:28:30

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'I'	System	15 Mar 2021 20:28:30

US3402381

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:24

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'I'	System	15 Mar 2021 20:28:30

US3402381

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '182.9' cm	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '91.6' kg	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered '27.38218'	System	16 Mar 2021 12:24:06
DataPoint set to visible.	System	15 Mar 2021 20:28:30

US3402381

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '182.9' cm	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '91.6' kg	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered '27.38218'	System	16 Mar 2021 12:24:06
DataPoint set to visible.	System	15 Mar 2021 20:28:30

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User closed query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 15Mar2021,However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:53:19
Query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 15Mar2021,However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 12:39:26
User opened query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 15Mar2021,However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:43:38
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06
	(b) (4)	

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '13:25'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered '15 Mar 2021 13:25'	System	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '36.1' C	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06
	(b) (4)	

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered empty.	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '70'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'bpm'	System	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '16'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'breaths/min'	System	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '118'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06
	(b) (4)	

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'mmHg'	System	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '70'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'mmHg'	System	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '182.9' cm	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '91.6' kg	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered '27.38218'	System	16 Mar 2021 12:24:06
DataPoint set to visible.	System	15 Mar 2021 20:28:30

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06
	(b) (4)	

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '14:23'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered '15 Mar 2021 14:23'	System	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '36.6' C	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06
	(b) (4)	

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered empty.	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '72'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'bpm'	System	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '16'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'breaths/min'	System	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '112'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'mmHg'	System	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '64'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:24:06

US3402381

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'mmHg'	System	16 Mar 2021 12:24:06

US3402381

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:22:16

US3402381

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:22:16

US3402381

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:25:40

US3402381

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered empty.	(b) (4)	16 Mar 2021 12:25:40
	Tammy Kohn (b) (4)	
	(b) (4)	

US3402381

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

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 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered empty.	Tammy Kohn (b) (4)	16 Mar 2021 12:25:40

US3402381

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'mRNA-1273'	System	16 Mar 2021 12:25:40
DataPoint set to visible.	System	15 Mar 2021 20:28:30

US3402381

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:25:40
	(b) (4)	

US3402381

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '13:52'	(b) (4)	16 Mar 2021 12:25:40
	Tammy Kohn (b) (4)	
	(b) (4)	

US3402381

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered '15 Mar 2021 13:52'	System	16 Mar 2021 12:25:40

US3402381

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Left Arm (LEFT ARM)'	Tammy Kohn (b) (4)	16 Mar 2021 12:25:40

US3402381

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'ONCE'	System	16 Mar 2021 12:25:40

US3402381

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'INTRAMUSCULAR'	System	16 Mar 2021 12:25:40

US3402381

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:19:42

US3402381

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:19:42
	(b) (4)	

US3402381

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '15:05'	(b) (4)	16 Mar 2021 12:19:42
	Tammy Kohn (b) (4)	
	(b) (4)	

US3402381

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered '15 Mar 2021 15:05'	System	16 Mar 2021 12:19:42

US3402381

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:21:59

US3402381

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:21:59

US3402381

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered '15:06'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:21:59

US3402381

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:24

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered '15 Mar 2021 15:06'	System	16 Mar 2021 12:21:59

US3402381

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

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
User entered 'Yes (Y)'	(b) (4)	16 Mar 2021 12:22:04
	Tammy Kohn (b) (4)	
	(b) (4)	

US3402381

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

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:57:16
User entered 'I'	System	16 Mar 2021 12:22:04

US3402381

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered 'Yes (Y)'	(b) (4)	29 Mar 2021 19:39:12
	Traci Hull (b) (4)	
	(b) (4)	

US3402381

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered '22 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	29 Mar 2021 19:39:12
	(b) (4)	

US3402381

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	29 Mar 2021 19:39:12

US3402381

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	29 Mar 2021 19:39:12
	(b) (4)	

US3402381

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:42:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	29 Mar 2021 19:39:18

US3402381

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:05
User entered 'I'	System	29 Mar 2021 19:39:18

US3402381

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:05
User entered 'I'	System	29 Mar 2021 19:39:18
DataPoint set to visible.	System	29 Mar 2021 19:39:18

US3402381

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	09 Apr 2021 18:51:54
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '9 Apr 2021'	Tammy Kohn (b) (4)	09 Apr 2021 18:51:54
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4)	09 Apr 2021 18:51:54
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:24

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	09 Apr 2021 18:51:54

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '9 Apr 2021'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '13:02'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User entered '9 Apr 2021 13:02'	System	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '36.7' C	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '68'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '18'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '108'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '68'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '9 Apr 2021'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '13:49'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User entered '9 Apr 2021 13:49'	System	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '36.9' C	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '88'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '18'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '120'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '86'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:37
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 18:53:37

US3402381

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:49
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '9 Apr 2021'	Tammy Kohn (b) (4)	09 Apr 2021 18:53:49
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	09 Apr 2021 18:54:56
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	09 Apr 2021 18:54:56
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	09 Apr 2021 18:54:56
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	09 Apr 2021 18:54:56
DataPoint set to visible.	System	29 Mar 2021 19:39:18

US3402381

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '9 Apr 2021'	Tammy Kohn (b) (4)	09 Apr 2021 18:54:56
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered '13:17'	Tammy Kohn (b) (4)	09 Apr 2021 18:54:56
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Apr 2021 13:17'	System	09 Apr 2021 18:54:56

US3402381

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Tammy Kohn (b) (4)	09 Apr 2021 18:54:56
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Apr 2021 18:54:56

US3402381

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:24

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Apr 2021 18:54:56

US3402381

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	09 Apr 2021 18:55:01
	(b) (4)	

US3402381

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:24

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 18:55:01

US3402381

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:28:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:51
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:49:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:59:41
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:45
User entered 'No (N)'	Traci Hull (b) (4)	10 Sep 2020 13:06:17

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:54:28
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:47:03
User entered	System	10 Nov 2020 16:46:57
'USA-US059-2020-mRNA-1273-P301000015'		
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 16:46:57

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 15:42:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 15:42:34
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 15:41:35
User entered 'Prostate Cancer'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '20 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:28
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	09 Apr 2021 19:01:20
DataPoint Un-verified.	System	09 Apr 2021 19:01:20
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	09 Apr 2021 19:01:20
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Tammy Kohn (b) (4)	09 Apr 2021 19:01:20
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 04:56:17
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'SUBJECTS CANCER TREATMENT IS STILL ONGOING' (Site from DM).	Tammy Kohn (b) (4)	16 Mar 2021 12:29:26
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 03:00:44
User closed query '*REQUERY* PV Query: Please assess the event end date after radiation has been completed (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. If event is to expected to not expected recover after radiation please state as such.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:56:27

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Ongoing?](#)

Audit	User	Time (GMT)
Query '*REQUERY* PV Query: Please assess the event end date after radiation has been completed (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. If event is to expected to not expected recover after radiation please state as such.' answered with 'Subject is still getting Medication and will be starting radiation in January' (Site from Safety).	Jennifer Molstead (b) (4)	29 Dec 2020 20:40:28
User opened query '*REQUERY* PV Query: Please assess the event end date after radiation has been completed (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. If event is to expected to not expected recover after radiation please state as such.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:27:36
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:26
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:33:47
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'SUBJECT WAS SEEN IN THE OFFICE TODAY. STATED HIS PROSTRATE CANCER IS STABILIZED AT THIS TIME WITH MEDICAITON' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 19:02:11
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 19:01:03
User entered '9 Apr 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 19:01:03
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 19:01:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:32:59
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'SUBJECT IS STIL BEING TREATED FOR THE PROSTATE CANCER' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 12:50:47
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 13:57:16
User closed query 'PV Query: Please assess the event end date after radiation has been completed (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. If event is to expected to not expected recover after radiation please state as such.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 18:40:40
Query 'PV Query: Please assess the event end date after radiation has been completed (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. If event is to expected to not expected recover after radiation please state as such.' answered with 'will update when further information is available' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 12:03:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please assess the event end date after radiation has been completed (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. If event is to expected to not expected recover after radiation please state as such.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 00:37:55
	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 23:07:06
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'their is no end date to provide as patient is undergoing radiation for the next 6 weeks' (Site from Safety).	Tammy Kohn (b) (4)	23 Nov 2020 16:07:13
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:02:46
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 00:12:22
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 00:12:22
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 00:11:40
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 00:11:06
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 00:11:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). User entered empty.	Jennifer Molstead (b) (4)	10 Nov 2020 00:10:41
	(b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
User closed query 'PV Query: (When information becomes available). Please assess the event end date after radiation has been completed (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. If event is to expected to not expected recover after radiation please state as such.' (Site from Safety). Query 'PV Query: (When information becomes available). Please assess the event end date after radiation has been completed (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. If event is to expected to not expected recover after radiation please state as such.' answered with 'Radiation has not begun yet once the patient begins and ends treatment I will go back and add date ok to close query for now.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:14:40
User opened query 'PV Query: (When information becomes available). Please assess the event end date after radiation has been completed (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. If event is to expected to not expected recover after radiation please state as such.' answered with 'Radiation has not begun yet once the patient begins and ends treatment I will go back and add date ok to close query for now.' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	05 Jan 2021 21:04:07
User opened query 'PV Query: (When information becomes available). Please assess the event end date after radiation has been completed (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. If event is to expected to not expected recover after radiation please state as such.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:30:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
Query 'PV Query: Since the event was medically treated, please confirm the severity. Please provide the rationale why the event is assessed as Grade 2.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:08:48
User opened query 'PV Query: Since the event was medically treated, please confirm the severity. Please provide the rationale why the event is assessed as Grade 2.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:38:35
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'I'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:31:05
Query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:04:06
User opened query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:03:49
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:44:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:44:05
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:22:10
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:28:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User closed query 'Per CDM re-query: Thank you for updating Relationship to IP as Not related as per previous query. However there is no update made for this field. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:10:12
User closed query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 23:07:24
Query 'Per CDM re-query: Thank you for updating Relationship to IP as Not related as per previous query. However there is no update made for this field. Please review and update as appropriate. Thank you' answered with 'updated to Not Related ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 16:05:37
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 16:04:27
User opened query 'Per CDM re-query: Thank you for updating Relationship to IP as Not related as per previous query. However there is no update made for this field. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:13:27
Query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	20 Nov 2020 21:14:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	20 Nov 2020 21:13:52
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 17:22:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 17:22:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Nov 2020 17:22:23
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 17:22:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	19 Nov 2020 17:22:07
User opened query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:06:33
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
Query 'PV Query: Please provide the rationale why the causality of prostate cancer with procedure is assessed as Not Applicable.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:09:09
User opened query 'PV Query: Please provide the rationale why the causality of prostate cancer with procedure is assessed as Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:38:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'I'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
Query 'Per DM CLR: RQ: Response noted, however, the recorded procedure is diagnostic and not therapeutic. Review response and update as appropriate. Otherwise, clarify.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:39:53
User opened query 'Per DM CLR: RQ: Response noted, however, the recorded procedure is diagnostic and not therapeutic. Review response and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 03:02:32
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the recorded procedure that match this AE was a Diagnostic procedure rather than a Therapeutic procedure. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 18:35:21
Query 'Per DM CLR: Other Action Taken = ConProc. However, the recorded procedure that match this AE was a Diagnostic procedure rather than a Therapeutic procedure. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'This is the only procedure that has currently been performed' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 12:01:56
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the recorded procedure that match this AE was a Diagnostic procedure rather than a Therapeutic procedure. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 17:23:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'I'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:34
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:33:51
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'SUBJECT WAS SEEN IN THE OFFICE TODAY. STATED HIS PROSTRATE CANCER IS STABILIZED AT THIS TIME WITH MEDICATION' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 19:02:46
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 19:01:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 19:01:03
User closed query 'Per source, the outcome is "Not Recovered/Not Resolved". If resolved please update source and add End Date and update "Ongoing" fields in source and EDC. Please review and update entries. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 20:41:44
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 19:01:50

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:33:06
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'SUBJECT IS STILL BEING TREATED FOR THE PROSTATE CANCER' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 12:50:40
Query 'Per source, the outcome is "Not Recovered/Not Resolved". If resolved please update source and add End Date and update "Ongoing" fields in source and EDC. Please review and update entries. Thank you!' answered with 'SUBJECT IS STILL BEING TREATED FOR THE PROSTATE CANCER' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 12:50:38
User opened query 'Per source, the outcome is "Not Recovered/Not Resolved". If resolved please update source and add End Date and update "Ongoing" fields in source and EDC. Please review and update entries. Thank you!' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 16:17:17
Query 'Per source, the outcome is "Not Recovered/Not Resolved". Please review and update entries.' canceled (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 16:16:28
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:15:12
User opened query 'Per source, the outcome is "Not Recovered/Not Resolved". Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 18:15:08
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 13:57:32

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please reassess the outcome after the subject completes radiation.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 21:14:46
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please reassess the outcome after the subject completes radiation.' answered with 'The patient has not begun radiation treatment as of yet. Ok to close this until the patient completes treatment and I will go back and update' (Site from Safety).	Tammy Kohn (b) (4)	05 Jan 2021 21:05:18
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please reassess the outcome after the subject completes radiation.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:29:26
User closed query '*REQUERY* PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please reassess the outcome after the subject completes radiation.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:59:10
Query '*REQUERY* PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please reassess the outcome after the subject completes radiation.' answered with 'Subject is starting radiation in January' (Site from Safety).	Jennifer Molstead (b) (4)	29 Dec 2020 20:43:09
User opened query '*REQUERY* PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please reassess the outcome after the subject completes radiation.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:26:48

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please reassess the outcome after the subject completes radiation.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 18:40:57
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please reassess the outcome after the subject completes radiation.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	22 Dec 2020 12:03:18
DataPoint Un-verified.	Jennifer Molstead (b) (4)	22 Dec 2020 12:02:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	22 Dec 2020 12:02:47
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please reassess the outcome after the subject completes radiation.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:37:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 23:07:33
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'at this point this in not expected to resolve' (Site from Safety).	Jennifer Molstead (b) (4)	23 Nov 2020 21:11:44

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:03:13
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:22:50
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:12:22
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:12:22
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	10 Nov 2020 00:12:22
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:11:40
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:11:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	10 Nov 2020 00:11:40
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:11:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	10 Nov 2020 00:11:06
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:10:41
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	10 Nov 2020 00:10:41
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23

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Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4)	10 Nov 2020 00:22:50
	(b) (4)	
User entered 'Subject was diagnosed with Prostate cancer 05Nov2020 after having a biopsy 30Oct2020. Subject began having symptoms of blood in sperm 20Sep2020. Subject went to Urologist. After Biopsy results'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:58
User closed query 'Per CDM re-query: Response noted; However please reconcile the dosage recorded in narrative and Con med. CM eCRF contains FIRMAGON of 240 mg dosage and narrative also includes FIRMAGON 80 mg. Please reconcile and clarify if another medication with different dosage need to be added else please review if narrative needs to be updated. Please update as appropriate else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:31:45
Query 'Per CDM re-query: Response noted; However please reconcile the dosage recorded in narrative and Con med. CM eCRF contains FIRMAGON of 240 mg dosage and narrative also includes FIRMAGON 80 mg. Please reconcile and clarify if another medication with different dosage need to be added else please review if narrative needs to be updated. Please update as appropriate else clarify.' answered with 'subject is on 80 mg' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:42:27
User closed query 'er DM CLR: SAE Narrative = WILL GO BACK MONTHLY FOR FURTHER INJECTIONS OF FIRMAGON 80MG. However, please confirm if the patient already had another injection. If yes, please recorded this in the ConMed eCRF. Update applicale eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 03:16:54
User opened query 'Per CDM re-query: Response noted; However please reconcile the dosage recorded in narrative and Con med. CM eCRF contains FIRMAGON of 240 mg dosage and narrative also includes FIRMAGON 80 mg. Please reconcile and clarify if another medication with different dosage need to be added else please review if narrative needs to be updated. Please update as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 03:16:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'er DM CLR: SAE Narrative = WILL GO BACK MONTHLY FOR FURTHER INJECTIONS OF FIRMAGON 80MG. However, please confirm if the patient already had another injection. If yes, please recorded this in the ConMed eCRF. Update applicale eCRF as appropriate. ' answered with 'This will be considered an ongoing medication this is already lusted as such' (Site from DM). User opened query 'er DM CLR: SAE Narrative = WILL GO BACK MONTHLY FOR FURTHER INJECTIONS OF FIRMAGON 80MG. However, please confirm if the patient already had another injection. If yes, please recorded this in the ConMed eCRF. Update applicale eCRF as appropriate. ' (Site from DM).	Jennifer Molstead (b) (4)	22 Dec 2020 12:03:52
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 04:57:11
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:36
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:32
User entered 'SUBJECT WAS DIAGNOSED WITH PROSTATE CANCER 05NOV2020 AFTER HAVING A BIOPSY 30OCT2020. SUBJECT BEGAN HAVING SYMPTOMS OF BLOOD IN SPERM 20SEP2020. SUBJECT WENT TO UROLOGIST. AFTER BIOPSY RESULTSSUBJECT WAS GIVRN 240 MG OF FIRMAGON SUB CUTANEOUSLY. AND WILL GO BACK MONTHLY FOR FURTHER INJECTIONS OF FIRMAGON 80MG. SUBJECT WILL ALSO BEGIN RADIATION IN APPROXIMATELY 6 WEEKS. This was entered with in 24 hours of site awareness' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	24 Nov 2020 15:54:28
	(b) (4)	20 Nov 2020 21:12:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS DIAGNOSED WITH PROSTATE CANCER 05NOV2020 AFTER HAVING A BIOPSY 30OCT2020. SUBJECT BEGAN HAVING SYMPTOMS OF BLOOD IN SPERM 20SEP2020. SUBJECT WENT TO UROLOGIST. AFTER BIOPSY RESULTSSUBJECT WAS GIVRN 240 MG OF FIRMAGON SUB CUTANEOUSLY. AND WILL GO BACK MONTHLY FOR FURTHER INJECTIONS OF FIRMAGON 80MG. SUBJECT WILL ALSO BEGIN RADIATION IN APPROXIMATELY 6 WEEKS.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	10 Nov 2020 00:22:50
User entered 'Subject was givrn 240 mg of Firmagon Sub cutaneously. And will go back monthly for further injections of Firmagon 80mg. Subject will also begin radiation in approximately 6 weeks.'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 15:41:23

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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	09 Nov 2020 15:41:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:28:24

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:51
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:59:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:22:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:24:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:24:16
Data point term sent to Coder User entered 'LISINOPRIL'	System (b) (4), (b) (6)	16 Aug 2020 19:24:00 16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '2.5'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 17:53:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:31:41
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:23:12
User entered 'UN UNK 2009'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 19:24:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 19:24:16
	(b) (4)	
Data point term sent to Coder	System	16 Aug 2020 19:24:00
User entered 'METOPROLOL'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '25'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'twice daily (BID)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:22:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:31:48
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:24:00
User entered 'UN UNK 2009'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 19:26:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 19:26:16
	(b) (4)	
Data point term sent to Coder	System	16 Aug 2020 19:25:01
User entered 'ASPIRIN'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'CARDIAC PROPHYLAXIS'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '81'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:22:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:31:54
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:24:32
User entered 'UN UNK 2009'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 19:27:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 19:27:16
	(b) (4)	
Data point term sent to Coder	System	16 Aug 2020 19:26:01
User entered 'ATORVASTATIN'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '40'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:22:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:32:00
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:25:08
User entered 'UN UNK 2013'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN, PRODUCTSYNONYM: NAPROSYN [NAPROXEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 06:50:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 06:50:21
Data point term sent to Coder	System	16 Aug 2020 19:26:01
User entered 'NAPROSYN (NAPROXEN)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'CHRONIC BACK PAIN'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '500'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:23:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:32:05
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:25:47
User entered 'UN UNK 2009'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 06:43:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 06:43:29
	(b) (4)	
Data point term sent to Coder	System	16 Aug 2020 19:28:02
User entered 'PROBIOTIC'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'DIGESTIVE DISTRESS'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '2'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:29:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:32:11
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:28:00
User entered 'UN UNK 2015'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: OTHER HORMONE ANTAGONISTS AND RELATED AGENTS, PRODUCT: DEGARELIX ACETATE, PRODUCTSYNONYM: FIRMAGON - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Nov 2020 15:58:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Nov 2020 15:58:33
Data point term sent to Coder	System	09 Nov 2020 15:42:38
User entered 'Firmagon'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Prostate Cancer'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '240'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
	(b) (4)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:10:20
	(b) (4)	
DataPoint Un-verified.	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:42
	(b) (4)	
User entered 'every month (QM)' reason for change:	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:42
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
	(b) (4)	
User entered 'once (ONCE)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
required.	(b) (4)	
DataPoint inactivated with code reason code Data not	(b) (4), (b) (6)	16 Aug 2020 19:31:35
required.	(b) (4)	

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '05 Nov 2020'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
	(b) (4)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:40:45
	(b) (4)	
User closed query 'Per source, please provide an end date.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 17:40:29
	(b) (4)	
Query 'Per source, please provide an end date.' answered with 'data updated' (Site from CRA).	Tammy Kohn (b) (4)	23 Jan 2021 12:18:44
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 12:18:36
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Tammy Kohn (b) (4)	23 Jan 2021 12:18:36
	(b) (4)	
User opened query 'Per source, please provide an end date.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 18:11:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:10:29
	(b) (4)	
DataPoint Un-verified.	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:31
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
	(b) (4)	
User entered 'No (N)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35
	(b) (4)	

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
	(b) (4)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:40:45
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 12:18:36
	(b) (4)	
User entered '05 Nov 2020' reason for change: New Information	Tammy Kohn (b) (4)	23 Jan 2021 12:18:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:11:09
	(b) (4)	
DataPoint Un-verified.	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:31
	(b) (4)	
User entered empty; reason for change New Information	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
	(b) (4)	
User entered '05 Nov 2020'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35
	(b) (4)	

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User entered '1'	System	22 Dec 2020 12:04:42
User entered empty.	System	09 Nov 2020 15:42:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User entered '1'	System	22 Dec 2020 12:04:42
User entered empty.	System	09 Nov 2020 15:42:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:31:35
User entered '802 (802)'	System	22 Dec 2020 12:04:42
User entered empty.	System	09 Nov 2020 15:42:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: HYPOTHALAMIC HORMONES, ATC: ANTI-GONADOTROPIN-RELEASING HORMONES, PRODUCT: RELUGOLIX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Mar 2021 06:27:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 06:27:27
Data point term sent to Coder	System	16 Mar 2021 12:28:53
User entered 'ORGOVYX'	Tammy Kohn (b) (4)	16 Mar 2021 12:28:35
	(b) (4)	

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered 'PROSTATE CANCER'	Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered '120'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered empty.	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered 'once daily (QD)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered empty.	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered empty.	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered '5 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered '0'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered empty.	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 12:28:35

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:28:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:51
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:10
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:41
User entered 'No (N)'	Traci Hull (b) (4)	10 Sep 2020 13:06:23

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:25
User entered '30 Oct 2020'	Jennifer Molstead (b) (4)	09 Nov 2020 15:43:02
	(b) (4)	

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:25
User entered 'Prostate Biopsy'	Jennifer Molstead (b) (4)	09 Nov 2020 15:43:02
	(b) (4)	

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:03:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:43:02
	(b) (4)	

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:24

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:43:02

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered		
'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 15:34:17
User entered '5'	System	22 Dec 2020 18:42:01
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered		
'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 15:34:17
User entered '5'	System	22 Dec 2020 18:42:01
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:28:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:16:10
User entered '10/Nov/2020 11:55'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:28:24

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.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered		
'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 15:34:17
User entered '5'	System	22 Dec 2020 18:42:01
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:28:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:16:10
User entered '19/Nov/2020 16:23'	System	19 Nov 2020 16:23:41

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:28:24

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.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 17:52:00
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 16:23:41

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered	System	10 Nov 2020 16:46:57
'USA-US059-2020-MRNA-1273-P301000015'		

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 15:34:17
User entered '5'	System	22 Dec 2020 18:42:01
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:28:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:16:10
User entered '20/Nov/2020 17:52'	System	20 Nov 2020 17:52:09

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:28:24

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.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:42:05
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 17:52:09

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered		
'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 15:34:17
User entered '5'	System	22 Dec 2020 18:42:01
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:28:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:16:10
User entered '23/Nov/2020 09:44'	System	23 Nov 2020 14:44:56

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:28:24

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.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:42:05
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 14:44:56

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered		
'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 15:34:17
User entered '5'	System	22 Dec 2020 18:42:01
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:28:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:16:10
User entered '22/Dec/2020 13:42'	System	22 Dec 2020 18:42:01

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:28:24

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.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:42:05
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 18:42:01

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered		
'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

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[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

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Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

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[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

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Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

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[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 15:34:17
User entered '5'	System	22 Dec 2020 18:42:01
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:28:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:09:20
User entered '12/Apr/2021 11:34'	System	12 Apr 2021 15:34:17

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Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

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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.	Frank Eder (b) (4)	26 Apr 2021 23:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:09:21
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 15:34:17