

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**

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[Participant ID](#)

US3402381

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

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US3402381

Folder: Screening

Form: Visit Date

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

Generated On: 09 Jun 2021 17:28:24

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 16 AUG 2020

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

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Folder OID SCRN

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US3402381

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

US3402381

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 (*dd MMM yyyy*) 16 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3402381

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

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Did the participant meet all eligibility criteria?

Yes

No

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US3402381

Folder: Screening

Form: Medical History Summary

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

Generated On: 09 Jun 2021 17:28:24

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Were any significant conditions reported?

Yes

No

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US3402381

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)	_____

US3402381

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)	_____

US3402381

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

US3402381

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)	_____

US3402381

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)	_____

US3402381

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)	_____

US3402381

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 <sup>2</sup>
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)	_____

US3402381

Folder: Screening

Form: Physical Examination

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

Generated On: 09 Jun 2021 17:28:24

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

16 AUG 2020

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

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US3402381

Folder: Screening

Form: Risk of Exposure

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

Generated On: 09 Jun 2021 17:28:24

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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

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

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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

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 16 AUG 2020

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

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Folder OID VISIT1

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US3402381

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

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Height	ND - Not Done
Weight	ND - Not Done

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US3402381

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 ( <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
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	54 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	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="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:39 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 13:39
Temperature ( <i>xxx.x</i> )	36.0 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	57 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG

US3402381

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

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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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US3402381

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

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 16 AUG 2020

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Collection time (*00:00-23:59*) 12:38 (24 HR)

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Collection date and time (derived) 16 AUG 2020 12:38

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US3402381

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

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

---

US3402381

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

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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

US3402381

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

US3402381

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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

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

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

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

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

PC Time Stamp	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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE in °F</b>	96.3 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	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.**  
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 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.**

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	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.**

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

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.**

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

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.**

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

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.**

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

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.**

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

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

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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

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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

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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

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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

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	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

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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

US3402381

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:24

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	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

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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

US3402381

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:24

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Yes

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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

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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

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Yes

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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

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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

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Yes

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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

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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

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   
No

---

Visit date (dd MMM yyyy) 14 SEP 2020

---

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

---

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 ( <i>dd MMM yyyy</i> )	14 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:02 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:02
Temperature ( <i>xxx.x</i> )	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	56 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	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 ( <i>dd MMM yyyy</i> )	14 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	12:16 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:16
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	49 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	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 ( <i>dd MMM yyyy</i> )	14 SEP 2020
Collection time ( <i>00:00-23:59</i> )	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

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Collection date ( <i>dd MMM yyyy</i> )			14 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	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

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**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	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.**

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

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.**

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	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.**

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 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.**

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

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.**

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	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.**

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

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.**

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	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

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

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

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   
No

---

Visit date (dd MMM yyyy) 12 OCT 2020

---

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

---

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  No

---

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 <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	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

Yes

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

No

Yes

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

Date and time of submission 03 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

Yes

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

No

Yes

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

Date and time of submission 21 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 <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 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   
Yes

Have you been exposed to someone with known SARS-CoV-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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 01 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#) 05 DEC 2020 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 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 10:17:01
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 <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	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

Yes

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

No

Yes

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

Date and time of submission 23 DEC 2020 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 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

<b>TIMEPOINT</b>	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 <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	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 <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	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

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<b>TIMEPOINT</b>	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 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

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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 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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   
Yes

Have you been exposed to someone with known SARS-CoV-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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 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 250

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

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

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

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 MAY 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 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  Yes

Have you been exposed to someone with known SARS-CoV-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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 MAY 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 278

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 MAY 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 285

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 MAY 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 292

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUN 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 299

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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08 JUN 2021 00:01

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12 JUN 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 306

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2021 00:01
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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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°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

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Date and time of submission

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22 JUN 2021 00:01

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26 JUN 2021 23:59

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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 320

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**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

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29 JUN 2021 00:01

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03 JUL 2021 23:59

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**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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

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Date and time of submission

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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 334

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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

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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   
Yes

Have you been exposed to someone with known SARS-CoV-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)**

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

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Date and time of submission

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20 JUL 2021 00:01

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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 348

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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US3402381

Folder: New Safety Follow Up Diary (1)

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**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 AUG 2021 00:01

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07 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 362

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

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

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

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

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

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

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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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  Yes

Have you been exposed to someone with known SARS-CoV-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)**

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Date and time of submission

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17 AUG 2021 00:01

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21 AUG 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

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**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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 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 383

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 SEP 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 390

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 SEP 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 397

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 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 404

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

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

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

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

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

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

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 SEP 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 411

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 OCT 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 418

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 05 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 09 OCT 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 425

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 12 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 16 OCT 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 432

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

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

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

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

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

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

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 OCT 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 439

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 26 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 30 OCT 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 446

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 NOV 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 453

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 NOV 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 460

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 NOV 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 467

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 NOV 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 474

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 DEC 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 481

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 DEC 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 488

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 14 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 18 DEC 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 495

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 21 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 25 DEC 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 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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 JAN 2022 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 509

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JAN 2022 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 516

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JAN 2022 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 523

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

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

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

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

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

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

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 JAN 2022 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 530

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 25 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#) 29 JAN 2022 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 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**

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

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Date and time of submission

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

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[Patient Cloud Close Date & Time](#) 05 FEB 2022 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 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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 FEB 2022 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 551

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 FEB 2022 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 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°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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 FEB 2022 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 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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 MAR 2022 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 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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAR 2022 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 579

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 MAR 2022 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 586

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 MAR 2022 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 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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 APR 2022 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 600

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 APR 2022 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 607

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

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

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

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

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

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

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 12 APR 2022 00:01

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[Patient Cloud Close Date & Time](#) 16 APR 2022 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 614

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

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

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

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

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

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

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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 APR 2022 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 621

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

26 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 APR 2022 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 628

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 MAY 2022 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 635

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 10 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#) 14 MAY 2022 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 642

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 MAY 2022 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 649

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAY 2022 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 656

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	31 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUN 2022 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 663

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 JUN 2022 00:01

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11 JUN 2022 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 670

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:28:24**

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

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[Patient Cloud Open Date & Time](#)

14 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JUN 2022 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 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)**

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**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JUN 2022 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 684

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

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

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

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

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

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

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 JUL 2022 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 691

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUL 2022 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 698

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUL 2022 23:59

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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

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**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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 JUL 2022 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 712

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

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

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

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

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

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

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)**

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**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

26 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 JUL 2022 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 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)**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 AUG 2022 00:01

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06 AUG 2022 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 726

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

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

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

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

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

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

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)**

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**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 AUG 2022 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 733

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

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

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

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

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

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

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 AUG 2022 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 740

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 AUG 2022 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 747

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 SEP 2022 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 754

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 SEP 2022 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 761

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 SEP 2022 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 768

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 SEP 2022 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 775

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 OCT 2022 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 782

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 OCT 2022 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 789

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402381**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 11 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#) 15 OCT 2022 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 796

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 OCT 2022 23:59

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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
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

---

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   
No

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   
Axillary   
Other

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   
No

---

Visit date (dd MMM yyyy) 15 MAR 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

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

US3402381

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.

---

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

AEID USA-US059-2020-MRNA-1273-P30  
1000015

Adverse event PROSTATE CANCER

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 20 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

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   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes   
No   
Unknown

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

---

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   
Related   
Not Applicable

---

Relationship to Study Procedure Not Related   
Related   
Not Applicable

---

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

---

Other action taken (check all that apply)

---

None False

---

Concomitant Medication True

---

Concomitant Procedure True

---

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with   
Sequelae   
Recovering/Resolving   
Unknown

---

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3402381

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

349 of 2070

US3402381

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3402381

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

US3402381

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   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3402381

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3402381

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   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3402381

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3402381

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   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3402381

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

US3402381

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 ( <i>dd MMM yyyy</i> )	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"/>

---

US3402381

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3402381

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 05 NOV 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

---

US3402381

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3402381

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

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-P30 1000015
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
<b>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.</b>	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
<b>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.</b>	<input checked="" type="checkbox"/> 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
<b>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.</b>	<input checked="" type="checkbox"/> 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
<b>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.</b>	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
<b>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.</b>	<input checked="" type="checkbox"/> 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
<b>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.</b>	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) (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:29

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) (b) (4)	08 Mar 2021 22:42:47
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (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 '1'	(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
	(b) (4)	

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) (b) (4)	08 Mar 2021 22:42:47
User entered 'Amendment 2 (2)'	Jennifer Molstead (b) (4) (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) (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (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) (b) (4)	08 Mar 2021 22:42:47
User entered empty.	Jennifer Molstead (b) (4) (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) (b) (4)	08 Mar 2021 22:42:47
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:40

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) (b) (4)	08 Mar 2021 22:42:47
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:40

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 '1'	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) (b) (4)	08 Mar 2021 22:42:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (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.	Coder Import (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)	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, HLG: 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, HLG: 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.	(b) (4) 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, HLG: 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 System	(b) (4)	16 Aug 2020 19:13:53
User entered 'CORONARY ARTERY DISEASE'	(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
	(b) (4)	
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 19:28:41
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

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'	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

[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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

[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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

[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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

**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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

**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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

[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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

[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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

**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

US3402381

Folder: Screening

Form: Risk of Exposure

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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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

[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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

**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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

**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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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 'Yes (Y)'	(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 'COMMUNITY ACQUIRED RISK'	(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

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

US3402381

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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

**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

US3402381

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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

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

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:24

[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 '1'	(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

US3402381

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

US3402381

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

US3402381

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

US3402381

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

US3402381

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

US3402381

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

US3402381

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

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:24

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

US3402381

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

US3402381

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

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:24

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

US3402381

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

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:24

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) (b) (4), (b) (6)	04 Nov 2020 16:08:03
Query 'Per CDM: This field requires yes or no. Please complete' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	03 Nov 2020 14:57:05
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	03 Nov 2020 14:56:59
User opened query 'Per CDM: This field requires yes or no. Please complete' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:33:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:33:27

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	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

[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	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 (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

US3402381

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

US3402381

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

US3402381

Folder: Visit 1 Day 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 '12:09'	(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

[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

US3402381

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

US3402381

Folder: Visit 1 Day 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) (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

[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 (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

US3402381

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

US3402381

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

US3402381

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

US3402381

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

US3402381

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	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 (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 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

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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) (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (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.	(b) (4) 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) (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4) (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'	(b) (4) 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) (b) (4)	15 Feb 2021 18:24:22
User entered '13:05'	Jennifer Molstead (b) (4) (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'	System	22 Aug 2020 23:39:48
User entered '97.1'	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-a0f3-2f5fcccc82ca'	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-a0f3-2f5fcccd82ca'	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-a0f3-2f5fcccc82ca'	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

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-a0f3-2f5fcccc82ca'	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' User entered '19 Aug 2020 20:54'	System	20 Aug 2020 00:54:07
	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'	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

**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'	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

**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)'	(b) (4) 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'	(b) (4) 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) (b) (4)	15 Feb 2021 18:24:22
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4) (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) (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4) (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)'	(b) (4) 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 '1'	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)'	(b) (4) 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'	(b) (4) 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.	(b) (4) 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)'	(b) (4) 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 '1'	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) (b) (4)	15 Feb 2021 18:24:22
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (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) (b) (4)	15 Feb 2021 18:24:22
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4) (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) (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4) (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)'	(b) (4) 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 '1'	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'	(b) (4) 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)'	(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

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'	(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 (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'	(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

[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	(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

[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

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'	(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 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)	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'	(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

[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'	(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

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'	(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

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'	(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

[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	(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

[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

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

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'	(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

[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'	(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

[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'	(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

[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)'	(b) (4) 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'	(b) (4) 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) (b) (4)	15 Feb 2021 18:24:22
User closed query 'Data is required. Please complete.' (Site from System).	System	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) (b) (4)	18 Sep 2020 16:42:18
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 16:11:26
User entered empty.	Jennifer Molstead (b) (4) (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 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) (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4) (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) (b) (4)	15 Feb 2021 18:24:22
User entered empty.	Jennifer Molstead (b) (4) (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'	(b) (4) 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

[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) (b) (4)	15 Feb 2021 18:24:22
User entered '11:38'	Jennifer Molstead (b) (4) (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'	(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 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'	(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 (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)'	(b) (4) 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'	(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 (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

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)'	(b) (4) 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'	System	18 Sep 2020 02:30:46
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'	System	21 Sep 2020 01:24:39
User entered '97.7'	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' User entered '20 Sep 2020 21:25'	System	21 Sep 2020 01:25:10
	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'	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

**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'	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

**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'	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

**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'	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

**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'	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

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)	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'	(b) (4) 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.	(b) (4) 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)'	(b) (4) 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 '1'	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) 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

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'	(b) (4) Traci Hull (b) (4) (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)'	(b) (4) 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

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)'	(b) (4) 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 '1'	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'	(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

[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)'	(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

[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) Tammy Kohn (b) (4)	07 Oct 2020 13:29:20
	(b) (4)	

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)'	(b) (4) 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 '1'	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

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

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)'	(b) (4) 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)'	(b) (4) 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

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'	(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

[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

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)	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

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'	(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

[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'	(b) (4) 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'	(b) (4) 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'	(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

[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) Traci Hull (b) (4)	12 Oct 2020 16:16:16

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.	(b) (4) 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)'	(b) (4) 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'	(b) (4) 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'	(b) (4) Traci Hull (b) (4) (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)'	(b) (4) 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 '1'	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' User entered '18 Oct 2020 13:40:44'	System	18 Oct 2020 17:40:48
	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' User entered '17 Nov 2020 15:40:24'	System	17 Nov 2020 20:40:27
	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' User entered '21 Nov 2020 16:59:13'	System	21 Nov 2020 21:59:16
	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'	System	30 Dec 2020 00:42:58
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' User entered '05 Jan 2021 13:03:14'	System	05 Jan 2021 18:03:18
	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' User entered '27 Jan 2021 14:53:08'	System	27 Jan 2021 19:53:11
	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'	System	16 Mar 2021 15:42:14
User entered '11 Mar 2021 09:42:21'	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' User entered '04 May 2021 00:02:19'	System	04 May 2021 04:04:25
	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) (b) (4)	08 Mar 2021 22:30:06
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (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'	(b) (4) 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) (b) (4)	08 Mar 2021 22:30:06
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4) (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) (b) (4)	08 Mar 2021 22:30:06
User entered empty.	Jennifer Molstead (b) (4) (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) (b) (4)	08 Mar 2021 22:30:06
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (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
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
	[REDACTED]	
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
	[REDACTED]	

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
	[REDACTED]	
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
	[REDACTED]	

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
	[REDACTED]	
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
	[REDACTED]	
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) [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)'	Tammy Kohn (b) (4) (b) (4)	11 Jan 2021 20:50:59

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) [REDACTED]	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:22
User entered empty.	Tammy Kohn (b) (4) (b) (4)	11 Jan 2021 20:50:59

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
	[REDACTED]	
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 '1'	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)	29 Apr 2021 19:45:36
	[REDACTED]	
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 13:28:48
	(b) (4)	

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]	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) [REDACTED]	29 Apr 2021 19:45:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:42:22
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:28:48

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) [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 13:28:52

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 '1'	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

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) (b) (4)	26 Apr 2021 23:42:22
User entered '70'	Tammy Kohn (b) (4) (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) (b) (4)	26 Apr 2021 23:42:22
User entered '16'	Tammy Kohn (b) (4) (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) (b) (4)	26 Apr 2021 23:42:22
User entered '118'	Tammy Kohn (b) (4) (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) (b) (4)	26 Apr 2021 23:42:22
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (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

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)'	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

[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) (b) (4)	26 Apr 2021 23:35:12
User entered 'Amendment 6 or later (Amendment 6 or later)'	Tammy Kohn (b) (4) (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

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) (b) (4)	26 Apr 2021 23:35:12
User entered 'Placebo (Placebo)'	Tammy Kohn (b) (4) (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 '1'	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) (b) (4)	26 Apr 2021 23:35:12
User entered '91.6' kg	Tammy Kohn (b) (4) (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
	(b) (4)	

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) (b) (4)	26 Apr 2021 23:35:12
User entered '36.1' C	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

[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) (b) (4)	26 Apr 2021 23:35:12
User entered 'Oral (Oral)'	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

[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) (b) (4)	26 Apr 2021 23:35:12
User entered '70'	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

[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) (b) (4)	26 Apr 2021 23:35:12
User entered '16'	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

[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) (b) (4)	26 Apr 2021 23:35:12
User entered '118'	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

[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
	(b) (4)	

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) (b) (4)	26 Apr 2021 23:35:12
User entered '36.6' C	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

[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) (b) (4)	26 Apr 2021 23:35:12
User entered 'Oral (Oral)'	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

[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
	(b) (4)	

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) (b) (4)	26 Apr 2021 23:35:12
User entered '72'	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

[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) (b) (4)	26 Apr 2021 23:35:12
User entered '112'	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

[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

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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

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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
	(b) (4)	

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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) (b) (4)	26 Apr 2021 23:35:12
User entered empty.	Tammy Kohn (b) (4) (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 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.	(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 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

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) 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

[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)'	(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

[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) 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 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
	(b) (4)	

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) Tammy Kohn (b) (4)	16 Mar 2021 12:22:04

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 '1'	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) 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

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

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

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)	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 '1'	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) (b) (4)	26 Apr 2021 23:35:12
User entered '13:49'	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

[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 '1'	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) (b) (4)	09 Nov 2020 15:31:45
User entered 'No (N)'	Traci Hull (b) (4) (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 'USA-US059-2020-mRNA-1273-P301000015'	System	10 Nov 2020 16:46:57
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) (b) (4)	09 Nov 2020 15:42:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 15:42:34
Data point term sent to Coder	System	09 Nov 2020 15:41:35
User entered 'Prostate Cancer'	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 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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 15:41:23

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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) (b) (4)	15 Apr 2021 00:04:58
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Apr 2021 19:01:20
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 19:01:20
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 19:01:20
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Apr 2021 19:01:03
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) (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

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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) (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) (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) (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.'	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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	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

[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) (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)	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

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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

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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

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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

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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

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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

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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 '1'	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

[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

Form: Adverse Events (1)

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

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[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) (6)	19 Nov 2020 16:06:33
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

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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) (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 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 '1'	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)

Generated On: 09 Jun 2021 17:28:24

[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 STIL 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 STIL 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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[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). 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). DataPoint Un-verified.	(b) (4), (b) (6) Jennifer Molstead (b) (4)	22 Dec 2020 18:40:57 22 Dec 2020 12:03:18
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). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	01 Dec 2020 00:37:24 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). 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).	(b) (4), (b) (6) Jennifer Molstead (b) (4)	23 Nov 2020 23:07:33 23 Nov 2020 21:11:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:24

[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) (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) (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) (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) (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)

Generated On: 09 Jun 2021 17:28:24

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

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) (b) (4)	10 Nov 2020 00:22:50
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) (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

[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)

Generated On: 09 Jun 2021 17:28:24

[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).	Jennifer Molstead (b) (4)	22 Dec 2020 12:03:52
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).	(b) (4), (b) (6)	10 Dec 2020 04:57:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:36
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:32
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
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)	20 Nov 2020 21:12:02

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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 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)	(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)	(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

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	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

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 15:41:23

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US3402381

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

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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

[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

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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

[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

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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

[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

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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

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

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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

[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

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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

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

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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

[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

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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

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

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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

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.' answered with 'ONGOING' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 19:31:41
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

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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

[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

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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

[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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:23:12

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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) (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 'METOPROLOL'	System (b) (4), (b) (6)	16 Aug 2020 19:24:00 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.' answered with 'ONGOING' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 19:31:48
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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	16 Aug 2020 19:24:00

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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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:24:00

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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) (b) (4)	16 Aug 2020 19:26:16
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 19:26:16
Data point term sent to Coder User entered 'ASPIRIN'	System (b) (4), (b) (6)	16 Aug 2020 19:25:01 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)	24 Nov 2020 16:03:02
	(b) (4), (b) (6)	
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.' answered with 'ONGOING' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 19:31:54
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

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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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:24:32

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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) (b) (4)	16 Aug 2020 19:27:16
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 19:27:16
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.' answered with 'ONGOING' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 19:32:00
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

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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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:25:08

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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.' answered with 'ONGOING' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 19:32:05
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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:25:47

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:25:47

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:25:47

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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) (b) (4)	17 Aug 2020 06:43:29
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 06:43:29
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.' answered with 'ONGOING' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 19:32:11
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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:28:00

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:28:00

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:28:00

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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
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
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

[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
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
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

[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
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
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

[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
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
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

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
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
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

[Frequency](#)

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)	21 Jan 2021 18:10:20
DataPoint Un-verified.	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:42
User entered 'every month (QM)' reason for change: New Information	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once (ONCE)'	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

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
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
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

[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
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
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

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
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
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

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
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
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

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
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
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

[Ongoing?](#)

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)	26 Jan 2021 17:40:45
User closed query 'Per source, please provide an end date.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 17:40:29
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
DataPoint Un-verified.	(b) (4)	23 Jan 2021 12:18:36
User entered 'No (N)' reason for change: New Information	Tammy Kohn (b) (4)	23 Jan 2021 12:18:36
User opened query 'Per source, please provide an end date.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 18:11:06
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:10:29
DataPoint Un-verified.	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:31
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:31
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
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

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
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:41:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:40:45
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 12:18:36
User entered '05 Nov 2020' reason for change: New Information	Tammy Kohn (b) (4)	23 Jan 2021 12:18:36
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:11:09
DataPoint Un-verified.	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:31
User entered empty; reason for change New Information	Jennifer Molstead (b) (4)	22 Dec 2020 12:04:31
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
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

[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
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
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

[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.	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

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
	(b) (4)	

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'	(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 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
	(b) (4)	

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
	(b) (4)	

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
	(b) (4)	

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
	(b) (4)	

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
	(b) (4)	

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
	(b) (4)	

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
	(b) (4)	

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
	(b) (4)	

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
	(b) (4)	

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
	(b) (4)	

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
	(b) (4)	

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

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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

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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)'	(b) (4) Traci Hull (b) (4) (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) (b) (4)	09 Nov 2020 15:43:02

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) (b) (4)	09 Nov 2020 15:43:02

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) (b) (4)	09 Nov 2020 15:43:02

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)	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)	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)	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)	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)	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)	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 '1'	(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)	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
DataPoint Verified.	(b) (4) (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 '1'	(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)	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)	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)	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
DataPoint Verified.	(b) (4) (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 '1'	(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)	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)	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)	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)	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
DataPoint Verified.	(b) (4)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:42:05
User entered '1'	(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)	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)	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)	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
DataPoint Verified.	(b) (4)	21 Jan 2021 18:16:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:42:05
User entered '1'	(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)	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)	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)	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)	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)	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)	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 (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

US3402381

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

Form: Safety Report Form (6)

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)	16 Apr 2021 19:09:21
User entered '1'	(b) (4), (b) (6)	12 Apr 2021 15:34:17