

US3802218 (Prod: UPMC University Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:49:22

All time stamps listed in this document are displayed in GMT

US3802218

Form: Participant Creation

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

---

[Participant ID](#)

US3802218

---

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

---

---

US3802218

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3802218

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
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

US3802218

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3802218

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3802218

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3802218

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

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



US3802218

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Condition	DUST ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Condition	GENERALIZED RASH
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3802218

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Condition	ENRIONMENTAL ALLERGIES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Condition	HYPERTENSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Condition	ANXIETY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Condition	ENLARGED PROSTATE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	



US3802218

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Condition	HYPERTRIGLYCERIDES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Condition	HIGH CHOLOESTEROL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802218

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:20
Height ( <i>xxx.x</i> )	172 cm
Weight ( <i>xxx.x</i> )	245 lb
BMI ( <i>xxx.x</i> )	37.64320 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	96.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
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> )	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802218

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3802218

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

---

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

US3802218

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

<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)	True
<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)	False
<b>Other</b>	False
<b>Specify</b>	

US3802218

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 146137

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 ☐



US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Jan 2021 14:07:34

Generated On: 10 Jun 2021 09:49:22

Height	172 cm
Weight	245.5 lb

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Jan 2021 14:07:34

Generated On: 10 Jun 2021 09:49:22

Height	172 cm
Weight	245.5 lb
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)	11 SEP 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:20
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Jan 2021 14:07:34

Generated On: 10 Jun 2021 09:49:22

Height	172 cm
Weight	245.5 lb
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)	11 SEP 2020
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:21
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3802218

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 10:46 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 10:46

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

US3802218

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

10:34 (24 HR)

Collection date and time (derived)

11 SEP 2020 10:34

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:29	11 SEP 2020 10:29
Nasopharyngeal Swab 2	No		

US3802218

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

11 SEP 2020 11:26

PC Open Date & Time

11 SEP 2020 11:06

PC Close Date & Time

11 SEP 2020 13:36

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	11 SEP 2020 22:55
PC Open Date & Time	11 SEP 2020 14:31
PC Close Date & Time	12 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 20:39

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

---

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 21:57

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 14:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 14:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 00:09

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

17 SEP 2020 18:58

---

PC Open Date & Time

17 SEP 2020 12:00

---

PC Close Date & Time

18 SEP 2020 11:59

---



US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 11:27

PC Open Date & Time

11 SEP 2020 11:06

PC Close Date & Time

11 SEP 2020 13:36

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**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

11 SEP 2020 22:56

PC Open Date & Time

11 SEP 2020 14:31

PC Close Date & Time

12 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 15:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 17:10

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 14:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 14:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 18:24

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 18:59

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**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 ☐

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 11:27
PC Open Date & Time	11 SEP 2020 11:06
PC Close Date & Time	11 SEP 2020 13:36

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**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 ☐

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 22:57
PC Open Date & Time	11 SEP 2020 14:31
PC Close Date & Time	12 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 15:52
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 17:09
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 14:37
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 14:02
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:25
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

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 ☒

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

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



US3802218

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 19 SEP 2020 03:16

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3802218

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:49:22

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 03:16
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3802218

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

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*

PATIENT CONTACT  
ATTEMPTED ON THREE  
SEPARATE OCCASIONS.  
PATIENT WAS UNABLE TO BE  
REACHED.

US3802218

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802218

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

---

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 THREE ATTEMPTS  
UNSUCCESSFUL

---

*If Contact Not Made, please provide Comments*

---

US3802218

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802218

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Jan 2021 14:07:34

Generated On: 10 Jun 2021 09:49:22

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)	13 OCT 2020
Time of assessment (00:00-23:59)	10:43 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 10:43
Temperature (xxx.x)	95.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	108 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Jan 2021 14:07:34

Generated On: 10 Jun 2021 09:49:22

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)	13 OCT 2020
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:44
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3802218

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

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.*

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 11:12 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 11:12

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

US3802218

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

10:52 (24 HR)

Collection date and time (derived)

13 OCT 2020 10:52

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:48	13 OCT 2020 10:48
Nasopharyngeal Swab 2	No		

US3802218

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 11:46

PC Open Date & Time

13 OCT 2020 11:32

PC Close Date & Time

13 OCT 2020 14:02

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp	13 OCT 2020 21:50
PC Open Date & Time	13 OCT 2020 14:57
PC Close Date & Time	14 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 01:19

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

---

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.5 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

15 OCT 2020 18:41

---

PC Open Date & Time

15 OCT 2020 12:00

---

PC Close Date & Time

16 OCT 2020 11:59

---

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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 OCT 2020 17:22

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

18 OCT 2020 01:18

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp 19 OCT 2020 00:01

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 17:52

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59



US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 11:46

PC Open Date & Time

13 OCT 2020 11:32

PC Close Date & Time

13 OCT 2020 14:02

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**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

13 OCT 2020 21:49

PC Open Date & Time

13 OCT 2020 14:57

PC Close Date & Time

14 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 01:19

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 18:41

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 17:22

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 01:18

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 00:01

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 17:52

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**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 ☐

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 11:47
PC Open Date & Time	13 OCT 2020 11:32
PC Close Date & Time	13 OCT 2020 14:02

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**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 ☐

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 21:49
PC Open Date & Time	13 OCT 2020 14:57
PC Close Date & Time	14 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**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 ☒

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 01:20
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

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 ☒

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 18:42
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

104 of 2079

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

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

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

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 ☒

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 01:19
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

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 ☒

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 00:01
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

110 of 2079

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 17:53
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59



US3802218

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

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

Comments CONTACT ATTEMPTED ON  
10/20,10/21,10/22.

*If Contact Not Made, please provide Comments*

US3802218

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 OCT 2020

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

Comments  
If Contact Not Made, please provide Comments  
ATTEMPTED TO CONTACT  
PARTICIPANT 3 TIMES  
WITHOUT SUCCESS

US3802218

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802218

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	10:10 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 10:10
Temperature ( <i>xxx.x</i> )	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse ( <i>xxx</i> )	89 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3802218

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

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.*

US3802218

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	12 NOV 2020
-------------------------------	-------------

Collection time (00:00-23:59)	10:51 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	12 NOV 2020 10:51
------------------------------------	-------------------

US3802218

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 18:29:12

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 75
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 NOV 2020 23:56:54
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 04:04:40

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

06 DEC 2020 04:12:03

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 17:37:44
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 103

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 JAN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 JAN 2021 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

10 JAN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

14 JAN 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

24 JAN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 JAN 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

31 JAN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

04 FEB 2021 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 152

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

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

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

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

---

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 159

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

14 FEB 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 FEB 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 166

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 FEB 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 187

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

21 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

25 MAR 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 APR 2021 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

04 APR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 APR 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 11:57:50

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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

18 APR 2021 16:48:05

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 APR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 APR 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

09 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

13 MAY 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 MAY 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 MAY 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

30 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 JUN 2021 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

06 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 JUN 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

20 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 JUN 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 JUL 2021 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

01 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 AUG 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

08 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

12 AUG 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
---	-------------------

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

22 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

26 AUG 2021 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

29 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 SEP 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

05 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

09 SEP 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 OCT 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
---	-------------------

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 DEC 2021 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 DEC 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

02 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

06 JAN 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 JAN 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 JAN 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

30 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 FEB 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

06 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 FEB 2022 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 FEB 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

20 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 FEB 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 MAR 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

06 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 MAR 2022 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 MAR 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

20 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 MAR 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 MAR 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 APR 2022 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

10 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

14 APR 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

17 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

21 APR 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

24 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 APR 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

01 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 MAY 2022 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

08 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

12 MAY 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

15 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

19 MAY 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

22 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

26 MAY 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

29 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 JUN 2022 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

05 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

09 JUN 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

12 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

16 JUN 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 JUL 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

10 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

14 JUL 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

17 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

21 JUL 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 AUG 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2022 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 SEP 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

04 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 SEP 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

11 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

15 SEP 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

18 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 SEP 2022 23:59

---



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**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°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 ☐

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

02 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

06 OCT 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2022 23:59

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59



US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 OCT 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

30 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 NOV 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

---

US3802218

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

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

**US3802218**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 NOV 2022 23:59

---



US3802218

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:49:22

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		12 APR 2021 11:58:06

US3802218

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802218

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 14:07:33

Generated On: 10 Jun 2021 09:49:22

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

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

Comments  
If Contact Not Made, please provide Comments  
ATTEMPTED THREE TIMES.  
MAILBOX FULL. PARTICIPANT  
CALLED OUTSIDE OF WINDOW

US3802218

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:37:24

Generated On: 10 Jun 2021 09:49:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802218

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:37:24

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 15:39:14

Generated On: 10 Jun 2021 09:49:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

ATTEMPTED TO CALL TWICE  
AND EMAILED ONCE.

*If Contact Not Made, please provide Comments*



US3802218

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 15:39:14

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802218

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 19:22:41

Generated On: 10 Jun 2021 09:49:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3802218

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 19:22:41

Generated On: 10 Jun 2021 09:49:22

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3802218

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 19:22:41

Generated On: 10 Jun 2021 09:49:22

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.*

US3802218

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 19:22:41

Generated On: 10 Jun 2021 09:49:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 APR 2021

Collection time (00:00-23:59)

10:23 (24 HR)

Collection date and time (derived)

12 APR 2021 10:23

US3802218

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 19:22:40

Generated On: 10 Jun 2021 09:49:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3802218**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

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*

**US3802218**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**US3802218**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Data signed:** (b) (4) 28 Jan 2021 14:07:32

**Generated On: 10 Jun 2021 09:49:22**

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

**US3802218**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Data signed: (b) (4) 28 Jan 2021 14:07:32**

**Generated On: 10 Jun 2021 09:49:22**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3802218

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:37:24

Generated On: 10 Jun 2021 09:49:22

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

Visit date (dd MMM yyyy)	11 FEB 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3802218

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Date of updated informed consent (*dd MMM yyyy*) 11 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 11 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3802218

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:37:24

Generated On: 10 Jun 2021 09:49:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 FEB 2021

Collection time (00:00-23:59)

11:21 (24 HR)

Collection date and time (derived)

11 FEB 2021 11:21

US3802218

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 12:37:24

Generated On: 10 Jun 2021 09:49:22

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

US3802218

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 14:48:30

Generated On: 10 Jun 2021 09:49:22

AEID	USA-US098-2020-MRNA-1273-P30 1000001
Adverse event	PARAESOPHOGEAL HIATAL HERNIA WORSENING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	5 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	351 of 2079



US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 14:48:30

Generated On: 10 Jun 2021 09:49:22

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

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 14:48:30

Generated On: 10 Jun 2021 09:49:22

---

10/28/2020-ADMITTED PRIOR TO  
SURGERY-PAST MEDICAL  
HISTORY REPORT OF KNOWN  
PARAESOPHAGEAL HERNIA  
THAT HAS BEEN  
EXPERIENCING WORSENING  
SYMPTOMS. ADMITTED FOR A  
LAPAROSCOPIC REPAIR OF  
HERNIA. CXR:  
CARDIOMEDIASTINAL  
SILHOUETTE NOT ENLARGED,  
INCLUDING HIATAL HERNIA,  
PULMONARY VASCULAR  
MARKINGS NOT ENLARGED,  
LUNG VOLUMES NORMAL, NO  
FOCAL CONSOLIDATION,  
PLEURAL EFFUSION OR  
SIGNIFICANT  
PNEUMOTHORAX. NO ACUTE  
OSSEOUS OR SOFT TISSUE  
ABNORMALITIES  
10/29/2020- VS 37.0, 97/62, 76, 16,  
93%, 108KG, 34.9BMI  
10/30/2020- REPAIR HIATAL  
HERNIA LAPROSCOPIC,  
ESOPHOGOSCOPY,  
GASTROPEXY, ESTIMATED  
BLOOD LOSS 10ML, FINDINGS:  
GIANT PARAESOPHOGEAL  
HERNIA WITH MAJORITY OF  
STOMACH INTRATHORACIC  
LAP GPEH REPAIR WITH  
GASTROPEXY, HIATAL  
CLOSURE WITH 2 POSTERIOR  
STITCHES AND 3 STITCHES AT

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 14:48:30

Generated On: 10 Jun 2021 09:49:22

---

3:00, LEFT PIGTAIL. VS 36.6,  
115/60, 84, 16, 97%  
10/31/2020- NO ACUTE EVENTS  
OVERNIGHT, ADEQUATE PAIN  
CONTROL. CXR: SMALL  
AMOUNT OF LEFT  
SUBPULMONIC EFFUSION LEFT  
PIGTAIL CATHETER REMAINS  
IN PLACE.  
11/1/2020- VS 37.5, 84/52, 64, 17,  
95%, CONTINUE INPATIENT  
CARE

---

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

---

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

---

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

Yes ☒

No ☐

---

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

---

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication TRIUMEQ 600MG/50MG/300MG

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 600/50/300

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)

356 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

	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 2016	
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"/>

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

358 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

	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) _____		
Start date completely unknown		True
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"/>



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication GLIMEPIRIDE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE 2

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

360 of 2079

EAB) (1725)

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

	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) _____		
Start date completely unknown		True
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"/>

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐  
No ☒

Indication ENLARGED PROSTATE

Dose per administration 0.4

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)

362 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

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

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication HEART HEALTH

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

364 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

	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) _____		
Start date completely unknown		True
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"/>

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTRIGLYCERIDES

Dose per administration 48

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

366 of 2079

EAB) (1725)

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

	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) _____		
Start date completely unknown		True
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"/>



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication VENLAFAXINEER

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 150

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)

368 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

	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 2016	
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"/>

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication VENLAFAXINEER

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 75

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)

370 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

	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 2016	
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"/>

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

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)

372 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

	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) _____		
Start date completely unknown		True
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"/>

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication KENALOG OINTMENT 30G  
[TRIAMCINOLONE ACETONIDE]

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED RASH

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

374 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

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



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication LEVOCETIRIZINE

Prophylaxis Yes ☐  
No ☒

Indication DUST ALLERGIES

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

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

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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)

378 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

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

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication HEPARIN

Prophylaxis Yes ☒  
No ☐

Indication CLOT PREVENTION

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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)

380 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENT INFLUENZA INFECTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

382 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Mar 2021 14:54:12

Generated On: 10 Jun 2021 09:49:22

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		6 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 31 Mar 2021 19:50:40

Generated On: 10 Jun 2021 09:49:22

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 OCT 2020	PARAESOPHAGEAL HERNIA REPAIR	Adverse Event	
30 OCT 2020	LEFT PIGTAIL CATHETER	Adverse Event	
28 OCT 2020	CXR	Adverse Event	
31 OCT 2020	CXR	Adverse Event	

US3802218

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

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

US3802218

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 28 Jan 2021 14:07:32

Generated On: 10 Jun 2021 09:49:22

Date of study discontinuation/completion ( <i>dd MMM yyyy</i> )	
Reason for discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Complete <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Other <input type="checkbox"/>
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 <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Other <input type="checkbox"/>
If main cause of death is Other, specify	
Date of death ( <i>dd MMM yyyy</i> )	
Was autopsy performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 16:30:40

Generated On: 10 Jun 2021 09:49:22

SAEID	USA-US098-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 16:30:40

Generated On: 10 Jun 2021 09:49:22

SAEID	USA-US098-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/NOV/2020 17:24
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.	True

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 16:30:40

Generated On: 10 Jun 2021 09:49:22

SAEID	USA-US098-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 15:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 16:30:40

Generated On: 10 Jun 2021 09:49:22

SAEID	USA-US098-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/NOV/2020 07:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 16:30:40

Generated On: 10 Jun 2021 09:49:22

SAEID	USA-US098-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Feb 2021 16:30:40

Generated On: 10 Jun 2021 09:49:22

SAEID	USA-US098-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/FEB/2021 09:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3802218 (Prod: UPMC University Center)

**US3802218**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:49:22**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'US3802218'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 14:05:45

**US3802218**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:03

US3802218

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 14:05:46

**US3802218**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:08:03

**US3802218**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'SCRN'	System	11 Sep 2020 14:08:03



US3802218

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:22

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 14:05:47

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '64'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'YEARS'	System	11 Sep 2020 14:08:24

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered '64'	System	11 Sep 2020 14:08:42

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Male (M)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:22

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24



**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:22

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

**US3802218**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:49:22**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:24

US3802218

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:22

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 Sep 2020'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:42



**US3802218**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'Sep 2020'	System	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered '2020'	System	11 Sep 2020 14:08:42

**US3802218**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:49:22**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Amendment 3 (3)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:42

**US3802218**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:42

**US3802218**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:49:22**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:42

**US3802218**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:49:22**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:42

US3802218

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:22

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 14:05:46



US3802218

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:22

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'I'	System	11 Sep 2020 14:08:48

**US3802218**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:08:48

US3802218

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:49:22

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:09:11

US3802218

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: HIV infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 14:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:51:40
Data point term sent to Coder	System	11 Sep 2020 14:50:48
User entered 'HIV'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:50:13

**US3802218**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'UN UNK 2016'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:50:13

**US3802218**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:50:13

**US3802218**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:50:13

**US3802218**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:50:13
	(b) (4)	



**US3802218**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:50:13

**US3802218**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'Jan 2016'	System	11 Sep 2020 14:50:13

**US3802218**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered '2016'	System	11 Sep 2020 14:50:13

**US3802218**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 14:50:13

**US3802218**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 14:50:13

US3802218

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Dust allergy, LLT: Dust allergy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 15:18:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 15:18:37
Data point term sent to Coder	System	11 Sep 2020 15:17:33
User entered 'Dust Allergy'	Dominic Kramer (b) (4)	11 Sep 2020 15:16:46

**US3802218**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:16:46

**US3802218**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:16:46



**US3802218**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:16:46

**US3802218**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:16:46

**US3802218**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:16:46

**US3802218**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 15:16:46

**US3802218**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 15:16:46

**US3802218**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 15:16:46

**US3802218**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 15:16:46

US3802218

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 15:19:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 15:19:40
Data point term sent to Coder	System	11 Sep 2020 15:18:35
User entered 'Hiatal Hernia'	Dominic Kramer (b) (4)	11 Sep 2020 15:17:36
	(b) (4)	



**US3802218**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:49:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:17:36

**US3802218**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:17:36

**US3802218**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:17:36

**US3802218**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:49:22**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:17:36

**US3802218**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:17:36

**US3802218**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 15:17:36

**US3802218**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 15:17:36

**US3802218**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 15:17:36



**US3802218**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 15:17:36

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User closed query 'Per DM CLR: Please specify the location and type of Rash (Urticarial vs Non-urticarial). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 14:57:36
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Generalized rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 17:01:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 17:01:46
Data point term sent to Coder	System	13 Nov 2020 16:45:42
Coding entries removed.	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:45:39
User entered 'Generalized RASH' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:45:39
Query 'Per DM CLR: Please specify the location and type of Rash (Urticarial vs Non-urticarial). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'participant did not disclose this information ' (Site from DM).	Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:43:04
User opened query 'Per DM CLR: Please specify the location and type of Rash (Urticarial vs Non-urticarial). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:30:04
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:19:39

US3802218

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	11 Sep 2020 15:19:39
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 15:18:35
User entered 'Rash'	Dominic Kramer (b) (4)	11 Sep 2020 15:18:25
	(b) (4)	

**US3802218**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'UN UNK 2015'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:18:25

**US3802218**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:18:25

**US3802218**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:18:25

**US3802218**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:49:22**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:18:25

**US3802218**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:18:25



**US3802218**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'Jan 2015'	System	11 Sep 2020 15:18:25

**US3802218**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered '2015'	System	11 Sep 2020 15:18:25

**US3802218**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 15:18:25

**US3802218**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	11 Sep 2020 15:18:25

US3802218

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 04:38:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 04:38:33
Data point term sent to Coder	System	19 Oct 2020 19:22:27
User entered 'enrionmental allergies'	Jennifer Nagg (b) (4)	19 Oct 2020 19:21:38

**US3802218**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:21:38

**US3802218**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:21:38

**US3802218**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:21:38



**US3802218**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:49:22**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:21:38

**US3802218**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:21:38

**US3802218**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:21:38

**US3802218**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:21:38

**US3802218**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:21:38

**US3802218**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:21:38

US3802218

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 03:44:09
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Emily Carney Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4)	29 Oct 2020 15:41:30
' answered with 'Participant did not report taking a medication. This is what was reported but it is under the supervision of a physician. ' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	29 Oct 2020 09:34:20
' (Site from DM).		
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:23:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:23:22
Data point term sent to Coder	System	19 Oct 2020 19:22:27
User entered 'hypertension'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:21:58

**US3802218**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:21:58



**US3802218**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:21:58

**US3802218**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:21:58

**US3802218**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:49:22**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:21:58

**US3802218**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:21:58

**US3802218**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:21:58

**US3802218**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:21:58

**US3802218**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:21:58

**US3802218**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:21:58



US3802218

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:49:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Oct 2020 19:23:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 19:23:22
Data point term sent to Coder	System	19 Oct 2020 19:22:27
User entered 'diabetes type 2'	Jennifer Nagg (b) (4)	19 Oct 2020 19:22:19
	(b) (4)	

**US3802218**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:22:19

**US3802218**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:22:19

**US3802218**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:22:19

**US3802218**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:49:22**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:22:19

**US3802218**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:22:19

**US3802218**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:22:19

**US3802218**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:22:19



**US3802218**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:22:19

**US3802218**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:22:19

US3802218

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:49:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 19:24:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 19:24:26
Data point term sent to Coder	System	19 Oct 2020 19:23:29
User entered 'anxiety'	Jennifer Nagg (b) (4)	19 Oct 2020 19:22:37

**US3802218**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:22:37

**US3802218**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:22:37

**US3802218**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:22:37

**US3802218**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:49:22**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:22:37

**US3802218**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:22:37



**US3802218**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:22:37

**US3802218**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:22:37

**US3802218**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:22:37

**US3802218**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:22:37

US3802218

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:49:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:48:04
DataPoint Verified.		03 Nov 2020 18:48:00
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:42:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:42:28
Data point term sent to Coder	System	03 Nov 2020 18:41:42
Coding entries removed.	Emily Dougherty (b) (4) (b) (4)	03 Nov 2020 18:41:08
User entered 'Enlarged Prostate' reason for change: Data Entry Error	Emily Dougherty (b) (4) (b) (4)	03 Nov 2020 18:41:08
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatic disorder, LLT: Prostatic disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:24:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:24:26
Data point term sent to Coder	System	19 Oct 2020 19:23:30
User entered 'prostate problems'	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:23:04

**US3802218**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:23:04

**US3802218**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:23:04

**US3802218**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:23:04



**US3802218**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:49:22**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:23:04

**US3802218**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:23:04

**US3802218**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:23:04

**US3802218**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:23:04

**US3802218**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:23:04

**US3802218**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	19 Oct 2020 19:23:04

US3802218

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:49:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated triglycerides, PT: Hypertriglyceridaemia, LLT: Hypertriglyceridemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 22:27:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:27:35
Data point term sent to Coder	System	04 Nov 2020 20:44:37
User entered 'hypertriglycerides'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:43:42

**US3802218**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:43:42



**US3802218**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:43:42

**US3802218**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:43:42

**US3802218**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:49:22**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:43:42

**US3802218**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:43:42

**US3802218**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	04 Nov 2020 20:43:42

**US3802218**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	04 Nov 2020 20:43:42

**US3802218**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	04 Nov 2020 20:43:42

**US3802218**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	04 Nov 2020 20:43:42



US3802218

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:49:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	(b) (4) Coders Import (b) (4)	05 Nov 2020 05:17:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coders Import (b) (4) (b) (4)	05 Nov 2020 05:17:36
Data point term sent to Coders	System	04 Nov 2020 20:47:43
User entered 'high cholesterol'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:47:10

**US3802218**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:47:10

**US3802218**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:47:10

**US3802218**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:47:10

**US3802218**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:49:22**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:47:10

**US3802218**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:47:10

**US3802218**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	04 Nov 2020 20:47:10

**US3802218**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	04 Nov 2020 20:47:10



**US3802218**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	04 Nov 2020 20:47:10

**US3802218**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered empty.	System	04 Nov 2020 20:47:10

**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:28

**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '10:20'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:28

**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered '11 Sep 2020 10:20'	System	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '172' cm	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:28
DataPoint set to visible.	(b) (4) System	11 Sep 2020 14:08:48

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '245' lb	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:28
DataPoint set to visible.	(b) (4) System	11 Sep 2020 14:08:48



**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered '37.64320'	System	11 Sep 2020 15:15:28
DataPoint set to visible.	System	11 Sep 2020 14:08:48

**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'kg/m2'	System	11 Sep 2020 15:15:28
DataPoint set to visible.	System	11 Sep 2020 14:08:48

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '96.8' F	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Infrared'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28

**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '68'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:28

**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'bpm'	System	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '18'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:28



**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'breaths/min'	System	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '107'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:28

**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'mmHg'	System	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '69'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:28

**US3802218**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User entered 'mmHg'	System	11 Sep 2020 15:15:28

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47

US3802218

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47

**US3802218**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:49:22**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:09:23



**US3802218**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:49:22**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 Sep 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:09:23

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

**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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

**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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

[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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

**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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59



US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

**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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

[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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

**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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

**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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59



US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

**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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

**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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'I'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

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)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '0'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:47
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:15:59

US3802218

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:11:48

**US3802218**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 Sep 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:11:48



US3802218

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

[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 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:11:48

**US3802218**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'VISIT1'	System	11 Sep 2020 14:11:48

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:22

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 14:16:06

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:22

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '146137'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 14:16:06

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:22

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 14:16:06

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:22

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 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:18:41

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:22

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 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:18:41

US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:22

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:18:41



US3802218

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:22

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User closed query 'Diabetes is not listed in Medical History Form. Please verify and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:33:36
Query 'Diabetes is not listed in Medical History Form. Please verify and reconcile.' answered with 'added' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	19 Oct 2020 19:17:32
User opened query 'Diabetes is not listed in Medical History Form. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 03:13:37
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:18:41

**US3802218**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:49:22**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:18:41

**US3802218**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:49:22**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	19 Oct 2020 19:17:36
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 06:07:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:07:56

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '172' cm	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:22

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '245.5' lb	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '172' cm	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:22

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '245.5' lb	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User accepted default value 'Pre-Dose (PREDOSE)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13



US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '10:20'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '11 Sep 2020 10:20'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '96.8' F	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Infrared'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '68'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13



US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'bpm'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '18'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'breaths/min'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '107'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'mmHg'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '69'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'mmHg'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '172' cm	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13



US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:22

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '245.5' lb	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User accepted default value 'Post-Dose (POSTDOSE)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11:21'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '11 Sep 2020 11:21'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '97.1' F	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13



US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Infrared'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '65'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'bpm'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '18'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'breaths/min'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '99'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'mmHg'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '62'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:33:13



US3802218

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'mmHg'	System	11 Sep 2020 15:33:13

US3802218

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:33:25

US3802218

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:33:25

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:49:41
	(b) (4)	

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

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 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:49:41
	(b) (4)	

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 Sep 2020'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:49:41



US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '10:46'	(b) (4) Lalicia Roman (b) (4)	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '11 Sep 2020 10:46'	System	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'ONCE'	System	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 14:49:41

US3802218

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:56

US3802218

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '11 Sep 2020'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:56

**US3802218**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '10:34'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:18:56



**US3802218**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '11 Sep 2020 10:34'	System	11 Sep 2020 15:18:56

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:49:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:19:42

**US3802218**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:49:22**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '10:29'	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:19:42

**US3802218**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '11 Sep 2020 10:29'	System	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:19:42



**US3802218**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Dominic Kramer (b) (4)	11 Sep 2020 15:19:42

**US3802218**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered empty.	System	11 Sep 2020 15:19:42

US3802218

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:51:12

**US3802218**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '1'	System	11 Sep 2020 14:51:12

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:13', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af07f36f-07bf-4aa1-9b45-abe59dbc606c'	System	11 Sep 2020 15:26:39
User entered 'Yes (Y)'	System	11 Sep 2020 15:26:39

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af07f36f-07bf-4aa1-9b45-abe59dbc606c'	System	11 Sep 2020 15:26:39
User entered '97.1'	System	11 Sep 2020 15:26:39

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af07f36f-07bf-4aa1-9b45-abe59dbc606c'	System	11 Sep 2020 15:26:39
User entered 'No (N)'	System	11 Sep 2020 15:26:39



US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:35', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af07f36f-07bf-4aa1-9b45-abe59dbc606c'	System	11 Sep 2020 15:26:39
User entered '11 Sep 2020 11:26'	System	11 Sep 2020 15:26:39

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '11 Sep 2020 11:06'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '11 Sep 2020 13:36'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:54:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b596b9c5-f18f-4fbe-b2ab-09310a17e2f0'	System	12 Sep 2020 02:55:19
User entered 'Yes (Y)'	System	12 Sep 2020 02:55:19

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:54:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b596b9c5-f18f-4fbe-b2ab-09310a17e2f0'	System	12 Sep 2020 02:55:19
User entered '97.6'	System	12 Sep 2020 02:55:19

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:55:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b596b9c5-f18f-4fbe-b2ab-09310a17e2f0'	System	12 Sep 2020 02:55:19
User entered 'No (N)'	System	12 Sep 2020 02:55:19

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:55:12', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b596b9c5-f18f-4fbe-b2ab-09310a17e2f0'	System	12 Sep 2020 02:55:19
User entered '11 Sep 2020 22:55'	System	12 Sep 2020 02:55:19



US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '11 Sep 2020 14:31'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 2'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T20:39:32', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '638d6a32-bb93-4f16-a358-6b58f4cc99da'	System	13 Sep 2020 00:39:56
User entered 'Yes (Y)'	System	13 Sep 2020 00:39:56

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T20:39:41', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '638d6a32-bb93-4f16-a358-6b58f4cc99da'	System	13 Sep 2020 00:39:56
User entered '98.0'	System	13 Sep 2020 00:39:56

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T20:39:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '638d6a32-bb93-4f16-a358-6b58f4cc99da'	System	13 Sep 2020 00:39:56
User entered 'No (N)'	System	13 Sep 2020 00:39:56

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T20:39:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '638d6a32-bb93-4f16-a358-6b58f4cc99da'	System	13 Sep 2020 00:39:56
User entered '12 Sep 2020 20:39'	System	13 Sep 2020 00:39:56

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 14:49:41



US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 3'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T21:57:31', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'a7ca690d-cfc1-44ea-ba2c-c10c41e53a64'	System	14 Sep 2020 01:57:59
User entered 'Yes (Y)'	System	14 Sep 2020 01:57:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T21:57:42', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'a7ca690d-cfc1-44ea-ba2c-c10c41e53a64'	System	14 Sep 2020 01:57:59
User entered '98.6'	System	14 Sep 2020 01:57:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T21:57:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'a7ca690d-cfc1-44ea-ba2c-c10c41e53a64'	System	14 Sep 2020 01:57:59
User entered 'No (N)'	System	14 Sep 2020 01:57:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T21:57:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'a7ca690d-cfc1-44ea-ba2c-c10c41e53a64'	System	14 Sep 2020 01:57:59
User entered '13 Sep 2020 21:57'	System	14 Sep 2020 01:57:59

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 14:49:41



US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 4'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b23b66fe-cd41-4aae-a8cd-3f5f616db4d4'	System	14 Sep 2020 18:36:27
User entered 'Yes (Y)'	System	14 Sep 2020 18:36:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:13', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b23b66fe-cd41-4aae-a8cd-3f5f616db4d4'	System	14 Sep 2020 18:36:27
User entered '98.1'	System	14 Sep 2020 18:36:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:16', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b23b66fe-cd41-4aae-a8cd-3f5f616db4d4'	System	14 Sep 2020 18:36:27
User entered 'No (N)'	System	14 Sep 2020 18:36:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:21', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'b23b66fe-cd41-4aae-a8cd-3f5f616db4d4'	System	14 Sep 2020 18:36:27
User entered '14 Sep 2020 14:36'	System	14 Sep 2020 18:36:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 5'	System	11 Sep 2020 14:49:41



US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1d26d061-2c19-4921-9f27-71b2a29b9ae7'	System	15 Sep 2020 18:01:27
User entered 'Yes (Y)'	System	15 Sep 2020 18:01:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1d26d061-2c19-4921-9f27-71b2a29b9ae7' User entered '97.9'	System	15 Sep 2020 18:01:27
	System	15 Sep 2020 18:01:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1d26d061-2c19-4921-9f27-71b2a29b9ae7'	System	15 Sep 2020 18:01:27
User entered 'No (N)'	System	15 Sep 2020 18:01:27

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:19', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1d26d061-2c19-4921-9f27-71b2a29b9ae7'	System	15 Sep 2020 18:01:27
User entered '15 Sep 2020 14:01'	System	15 Sep 2020 18:01:27

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 6'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T00:09:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4298b35a-a76f-4c5f-9002-58d30c298712'	System	17 Sep 2020 04:09:24
User entered 'Yes (Y)'	System	17 Sep 2020 04:09:24



US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T00:09:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4298b35a-a76f-4c5f-9002-58d30c298712'	System	17 Sep 2020 04:09:24
User entered '98.1'	System	17 Sep 2020 04:09:24

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T00:09:14', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4298b35a-a76f-4c5f-9002-58d30c298712'	System	17 Sep 2020 04:09:24
User entered 'No (N)'	System	17 Sep 2020 04:09:24

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T00:09:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4298b35a-a76f-4c5f-9002-58d30c298712'	System	17 Sep 2020 04:09:24
User entered '17 Sep 2020 00:09'	System	17 Sep 2020 04:09:24

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 7'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:58:39', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '3741d864-ad5f-4e46-9c3d-93ffa0edd6cc'	System	17 Sep 2020 22:59:23
User entered 'Yes (Y)'	System	17 Sep 2020 22:59:23

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:58:48', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '3741d864-ad5f-4e46-9c3d-93ffa0edd6cc'	System	17 Sep 2020 22:59:23
User entered '98.1'	System	17 Sep 2020 22:59:23



US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:58:52', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '3741d864-ad5f-4e46-9c3d-93ffa0edd6cc'	System	17 Sep 2020 22:59:23
User entered 'No (N)'	System	17 Sep 2020 22:59:23

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:58:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '3741d864-ad5f-4e46-9c3d-93ffa0edd6cc'	System	17 Sep 2020 22:59:23
User entered '17 Sep 2020 18:58'	System	17 Sep 2020 22:59:23

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:47', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '09d506fc-02ba-45f1-b4a2-83a428c52114'	System	11 Sep 2020 15:27:08
User entered 'None (1)'	System	11 Sep 2020 15:27:08

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:51', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '09d506fc-02ba-45f1-b4a2-83a428c52114'	System	11 Sep 2020 15:27:08
User entered 'No (N)'	System	11 Sep 2020 15:27:08

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '09d506fc-02ba-45f1-b4a2-83a428c52114'	System	11 Sep 2020 15:27:08
User entered 'No (N)'	System	11 Sep 2020 15:27:08



US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:26:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '09d506fc-02ba-45f1-b4a2-83a428c52114'	System	11 Sep 2020 15:27:08
User entered 'None (1)'	System	11 Sep 2020 15:27:08

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:04', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '09d506fc-02ba-45f1-b4a2-83a428c52114'	System	11 Sep 2020 15:27:08
User entered '11 Sep 2020 11:27'	System	11 Sep 2020 15:27:08

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '11 Sep 2020 11:06'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '11 Sep 2020 13:36'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:55:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'ae892d38-ba7a-4d4b-b14c-f222c5590437'	System	12 Sep 2020 02:56:16
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 02:56:16

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:55:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'ae892d38-ba7a-4d4b-b14c-f222c5590437'	System	12 Sep 2020 02:56:16
User entered 'No (N)'	System	12 Sep 2020 02:56:16

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:55:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'ae892d38-ba7a-4d4b-b14c-f222c5590437'	System	12 Sep 2020 02:56:16
User entered 'No (N)'	System	12 Sep 2020 02:56:16



US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:55:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'ae892d38-ba7a-4d4b-b14c-f222c5590437'	System	12 Sep 2020 02:56:16
User entered 'None (1)'	System	12 Sep 2020 02:56:16

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:09', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'ae892d38-ba7a-4d4b-b14c-f222c5590437'	System	12 Sep 2020 02:56:16
User entered '11 Sep 2020 22:56'	System	12 Sep 2020 02:56:16

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '11 Sep 2020 14:31'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 2'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:52:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fcdd2e9e-738c-4c30-9f19-3b787057e7b2'	System	12 Sep 2020 19:52:41
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 19:52:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:52:24', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fcdd2e9e-738c-4c30-9f19-3b787057e7b2'	System	12 Sep 2020 19:52:41
User entered 'No (N)'	System	12 Sep 2020 19:52:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:52:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fcdd2e9e-738c-4c30-9f19-3b787057e7b2'	System	12 Sep 2020 19:52:41
User entered 'No (N)'	System	12 Sep 2020 19:52:41



US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:52:30', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fcdd2e9e-738c-4c30-9f19-3b787057e7b2'	System	12 Sep 2020 19:52:41
User entered 'None (1)'	System	12 Sep 2020 19:52:41

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:52:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fcdd2e9e-738c-4c30-9f19-3b787057e7b2'	System	12 Sep 2020 19:52:41
User entered '12 Sep 2020 15:52'	System	12 Sep 2020 19:52:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 3'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:46', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af406d91-0618-4db8-b683-bbeab74ff340'	System	13 Sep 2020 21:10:04
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 21:10:04

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af406d91-0618-4db8-b683-bbeab74ff340'	System	13 Sep 2020 21:10:04
User entered 'No (N)'	System	13 Sep 2020 21:10:04

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:52', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af406d91-0618-4db8-b683-bbeab74ff340'	System	13 Sep 2020 21:10:04
User entered 'No (N)'	System	13 Sep 2020 21:10:04



US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af406d91-0618-4db8-b683-bbeab74ff340'	System	13 Sep 2020 21:10:04
User entered 'None (1)'	System	13 Sep 2020 21:10:04

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:10:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'af406d91-0618-4db8-b683-bbeab74ff340'	System	13 Sep 2020 21:10:04
User entered '13 Sep 2020 17:10'	System	13 Sep 2020 21:10:04

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 4'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:29', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '331bde5c-e0a2-4fd3-9333-0c971adb62ab'	System	14 Sep 2020 18:36:51
User entered 'None (1)'	System	14 Sep 2020 18:36:51

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:32', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '331bde5c-e0a2-4fd3-9333-0c971adb62ab'	System	14 Sep 2020 18:36:51
User entered 'No (N)'	System	14 Sep 2020 18:36:51

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '331bde5c-e0a2-4fd3-9333-0c971adb62ab'	System	14 Sep 2020 18:36:51
User entered 'No (N)'	System	14 Sep 2020 18:36:51



US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:39', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '331bde5c-e0a2-4fd3-9333-0c971adb62ab'	System	14 Sep 2020 18:36:51
User entered 'None (1)'	System	14 Sep 2020 18:36:51

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '331bde5c-e0a2-4fd3-9333-0c971adb62ab'	System	14 Sep 2020 18:36:51
User entered '14 Sep 2020 14:36'	System	14 Sep 2020 18:36:51

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 5'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:25', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fdd98001-86d8-49d5-b45c-d65dea1743aa'	System	15 Sep 2020 18:01:42
User entered 'None (1)'	System	15 Sep 2020 18:01:42

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fdd98001-86d8-49d5-b45c-d65dea1743aa'	System	15 Sep 2020 18:01:42
User entered 'No (N)'	System	15 Sep 2020 18:01:42

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:30', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fdd98001-86d8-49d5-b45c-d65dea1743aa'	System	15 Sep 2020 18:01:42
User entered 'No (N)'	System	15 Sep 2020 18:01:42



US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fdd98001-86d8-49d5-b45c-d65dea1743aa'	System	15 Sep 2020 18:01:42
User entered 'None (1)'	System	15 Sep 2020 18:01:42

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:39', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'fdd98001-86d8-49d5-b45c-d65dea1743aa'	System	15 Sep 2020 18:01:42
User entered '15 Sep 2020 14:01'	System	15 Sep 2020 18:01:42

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 6'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:24:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8bdc7671-44a9-48c9-a9b3-10db4ce3caf1'	System	16 Sep 2020 22:24:58
User entered 'None (1)'	System	16 Sep 2020 22:24:58

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:24:43', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8bdc7671-44a9-48c9-a9b3-10db4ce3caf1'	System	16 Sep 2020 22:24:58
User entered 'No (N)'	System	16 Sep 2020 22:24:58

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:24:46', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8bdc7671-44a9-48c9-a9b3-10db4ce3caf1'	System	16 Sep 2020 22:24:58
User entered 'No (N)'	System	16 Sep 2020 22:24:58



US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:24:48', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8bdc7671-44a9-48c9-a9b3-10db4ce3caf1'	System	16 Sep 2020 22:24:58
User entered 'None (1)'	System	16 Sep 2020 22:24:58

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:24:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8bdc7671-44a9-48c9-a9b3-10db4ce3caf1'	System	16 Sep 2020 22:24:58
User entered '16 Sep 2020 18:24'	System	16 Sep 2020 22:24:58

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 7'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:05', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '83c384c9-6a26-4466-bbb8-47ab4efb317b'	System	17 Sep 2020 22:59:29
User entered 'None (1)'	System	17 Sep 2020 22:59:29

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '83c384c9-6a26-4466-bbb8-47ab4efb317b'	System	17 Sep 2020 22:59:29
User entered 'No (N)'	System	17 Sep 2020 22:59:29

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '83c384c9-6a26-4466-bbb8-47ab4efb317b'	System	17 Sep 2020 22:59:29
User entered 'No (N)'	System	17 Sep 2020 22:59:29



US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:14', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '83c384c9-6a26-4466-bbb8-47ab4efb317b'	System	17 Sep 2020 22:59:29
User entered 'None (1)'	System	17 Sep 2020 22:59:29

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:21', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '83c384c9-6a26-4466-bbb8-47ab4efb317b'	System	17 Sep 2020 22:59:29
User entered '17 Sep 2020 18:59'	System	17 Sep 2020 22:59:29

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:15', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:17', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:24', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'None (0)'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:28', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered 'No (N)'	System	11 Sep 2020 15:27:48

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T11:27:32', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'bc7e8cc1-7d33-4541-bb88-98bb6bae3247'	System	11 Sep 2020 15:27:48
User entered '11 Sep 2020 11:27'	System	11 Sep 2020 15:27:48

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '11 Sep 2020 11:06'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '11 Sep 2020 13:36'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 14:49:41



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:39', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:42', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:46', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:51', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'None (0)'	System	12 Sep 2020 02:57:12

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:56:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered 'No (N)'	System	12 Sep 2020 02:57:12

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-11T22:57:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'c8cd848b-4eb9-4933-8be2-1be1ce330e55'	System	12 Sep 2020 02:57:12
User entered '11 Sep 2020 22:57'	System	12 Sep 2020 02:57:12



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '11 Sep 2020 14:31'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 2'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:28', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'None (0)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:51:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered 'No (N)'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-12T15:52:12', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e8e7f807-1c27-4e9a-b42c-66619e62cb58'	System	12 Sep 2020 19:52:14
User entered '12 Sep 2020 15:52'	System	12 Sep 2020 19:52:14

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 3'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:08:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:08:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:07', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:10', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'None (0)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:13', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered 'No (N)'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-13T17:09:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '63add730-53a7-4580-b023-e25c890a3d49'	System	13 Sep 2020 21:09:43
User entered '13 Sep 2020 17:09'	System	13 Sep 2020 21:09:43

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 14:49:41



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 4'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:36:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:04', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:49:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:06', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'None (0)'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered 'No (N)'	System	14 Sep 2020 18:37:22



**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-14T14:37:15', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '538d5012-4413-4bc9-9790-102266c7c9bb'	System	14 Sep 2020 18:37:22
User entered '14 Sep 2020 14:37'	System	14 Sep 2020 18:37:22

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 5'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:43', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:47', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:52', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'None (0)'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:01:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered 'No (N)'	System	15 Sep 2020 18:02:10

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-15T14:02:05', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4e226ade-c1e7-4783-a53a-77b40fc94958'	System	15 Sep 2020 18:02:10
User entered '15 Sep 2020 14:02'	System	15 Sep 2020 18:02:10

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 6'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:24:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:04', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:06', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'None (0)'	System	16 Sep 2020 22:25:21

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:13', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered 'No (N)'	System	16 Sep 2020 22:25:21

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-16T18:25:17', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '61bcf273-953c-4ebd-9c44-ea128d1bae23'	System	16 Sep 2020 22:25:21
User entered '16 Sep 2020 18:25'	System	16 Sep 2020 22:25:21

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 14:49:41



**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 7'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:31', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'No interference with activity (1)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'None (0)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'None (0)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:42', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'None (0)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'None (0)'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:47', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'None (0)'	System	17 Sep 2020 23:00:03



US3802218

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered 'No (N)'	System	17 Sep 2020 23:00:03

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-17T18:59:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afa99a39-3ea8-49de-b2e1-6fa81f860188'	System	17 Sep 2020 23:00:03
User entered '17 Sep 2020 18:59'	System	17 Sep 2020 23:00:03

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 14:49:41

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 14:49:41

US3802218

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	17 Sep 2020 23:00:03
User entered 'Day 8'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:49:22

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-19T03:15:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8d5527aa-3c5b-4e6b-90fc-cc6e1ca79fc8'	System	19 Sep 2020 07:16:07
User entered 'None (0)'	System	19 Sep 2020 07:16:07

US3802218

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-19T03:16:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8d5527aa-3c5b-4e6b-90fc-cc6e1ca79fc8'	System	19 Sep 2020 07:16:07
User entered '19 Sep 2020 03:16'	System	19 Sep 2020 07:16:07

US3802218

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 23:00:03



**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	17 Sep 2020 23:00:03
User entered 'Day 8'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-19T03:16:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '13baba6f-6d6d-413e-8684-c24e84b88d3a'	System	19 Sep 2020 07:16:13
User entered 'No (N)'	System	19 Sep 2020 07:16:13

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-09-19T03:16:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '13baba6f-6d6d-413e-8684-c24e84b88d3a'	System	19 Sep 2020 07:16:13
User entered '19 Sep 2020 03:16'	System	19 Sep 2020 07:16:13

**US3802218**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 23:00:03

US3802218

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 23:00:03

**US3802218**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	21 Sep 2020 19:19:59

**US3802218**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '21 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	21 Sep 2020 19:19:59



US3802218

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Contact Not Made (CONTACT NOT MADE)'	Dominic Kramer (b) (4) (b) (4)	21 Sep 2020 19:19:59

US3802218

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Patient contact attempted on three separate occasions. Patient was unable to be reached.'	Dominic Kramer (b) (4)	21 Sep 2020 19:19:59

US3802218

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	21 Sep 2020 19:20:04

**US3802218**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'I'	System	21 Sep 2020 19:20:04

**US3802218**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	25 Sep 2020 19:09:46

US3802218

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '25 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	25 Sep 2020 19:09:46

US3802218

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dominic Kramer (b) (4)	25 Sep 2020 19:09:46

US3802218

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Dominic Kramer (b) (4)	25 Sep 2020 19:09:46



US3802218

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	25 Sep 2020 19:09:34

**US3802218**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '1'	System	25 Sep 2020 19:09:34

**US3802218**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	05 Oct 2020 12:49:04

**US3802218**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '5 Oct 2020' reason for change: Data Entry Error	Emily Dougherty (b) (4) (b) (4)	05 Oct 2020 18:27:04
User entered '4 Oct 2020'	Jennifer Nagg (b) (4) (b) (4)	05 Oct 2020 12:49:04

US3802218

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Emily Dougherty (b) (4)	05 Oct 2020 18:27:04
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jennifer Nagg (b) (4)	05 Oct 2020 12:49:04
	(b) (4)	

**US3802218**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Three attempts unsuccessful'	(b) (4) Jennifer Nagg (b) (4)	05 Oct 2020 12:49:04

**US3802218**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	05 Oct 2020 12:49:10

**US3802218**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'I'	System	05 Oct 2020 12:49:10



US3802218

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:26

US3802218

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '13 Oct 2020'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:00:26

US3802218

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

[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 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Clinic (Clinic)'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:00:26

**US3802218**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'VISIT2'	System	13 Oct 2020 15:00:26

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User accepted default value 'Pre-Dose (PREDOSE)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '13 Oct 2020'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '10:43'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11



US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '13 Oct 2020 10:43'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User closed query 'Per CDM-Requery: Site response noted, however, temperature is abnormal. Kindly confirm in the response if this is NCS or CS' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:22:11
Query 'Per CDM-Requery: Site response noted, however, temperature is abnormal. Kindly confirm in the response if this is NCS or CS' answered with 'ncs' (Site from DM).	Melissa Andrasko (b) (4) (b) (4)	14 Oct 2020 20:09:00
User opened query 'Per CDM-Requery: Site response noted, however, temperature is abnormal. Kindly confirm in the response if this is NCS or CS' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:56:04
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 06:51:53
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Actual value ' (Site from System).	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:52:57
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Oct 2020 15:51:11
User entered '95.2' F	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Other (Other)'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Infrared'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '108'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'bpm'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '18'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'breaths/min'	System	13 Oct 2020 15:51:11



US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '141'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'mmHg'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '84'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'mmHg'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User accepted default value 'Post-Dose (POSTDOSE)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '13 Oct 2020'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11:44'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11



US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '13 Oct 2020 11:44'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '96.8' F	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Infrared'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '84'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'bpm'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '18'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'breaths/min'	System	13 Oct 2020 15:51:11



US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '107'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'mmHg'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '74'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'mmHg'	System	13 Oct 2020 15:51:11

US3802218

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:31

US3802218

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:00:31

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	13 Oct 2020 15:16:41

**US3802218**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:49:22**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Lalicia Roman (b) (4)	13 Oct 2020 15:16:41



US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

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 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered empty.	Lalicia Roman (b) (4) (b) (4)	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '13 Oct 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '11:12'	(b) (4) Lalicia Roman (b) (4)	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '13 Oct 2020 11:12'	System	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lalicia Roman (b) (4)	13 Oct 2020 15:16:41
	(b) (4)	

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'ONCE'	System	13 Oct 2020 15:16:41

US3802218

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:22

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 15:16:41



US3802218

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:00:47

US3802218

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '13 Oct 2020'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:00:47

**US3802218**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '10:52'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:00:47

**US3802218**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '13 Oct 2020 10:52'	System	13 Oct 2020 15:00:47

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:49:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '13 Oct 2020'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:01:10

**US3802218**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:01:10

**US3802218**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:49:22**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '10:48'	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:01:10



**US3802218**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '13 Oct 2020 10:48'	System	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:10

**US3802218**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:49:22**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Dominic Kramer (b) (4)	13 Oct 2020 15:01:10

**US3802218**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered empty.	System	13 Oct 2020 15:01:10

US3802218

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	13 Oct 2020 15:01:16

**US3802218**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '1'	System	13 Oct 2020 15:01:16

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:07', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '219641e5-5506-4db1-8247-abd5aeb50217'	System	13 Oct 2020 15:46:31
User entered 'Yes (Y)'	System	13 Oct 2020 15:46:31

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:14', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '219641e5-5506-4db1-8247-abd5aeb50217'	System	13 Oct 2020 15:46:31
User entered '96.8'	System	13 Oct 2020 15:46:31

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:18', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '219641e5-5506-4db1-8247-abd5aeb50217'	System	13 Oct 2020 15:46:31
User entered 'No (N)'	System	13 Oct 2020 15:46:31

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:23', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '219641e5-5506-4db1-8247-abd5aeb50217'	System	13 Oct 2020 15:46:31
User entered '13 Oct 2020 11:46'	System	13 Oct 2020 15:46:31

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Oct 2020 11:32'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Oct 2020 14:02'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:50:07', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f24cf4ac-3318-451b-ac24-a7d82b208355'	System	14 Oct 2020 01:50:40
User entered 'Yes (Y)'	System	14 Oct 2020 01:50:40



US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:50:25', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f24cf4ac-3318-451b-ac24-a7d82b208355'	System	14 Oct 2020 01:50:40
User entered '97.1'	System	14 Oct 2020 01:50:40

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:50:28', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f24cf4ac-3318-451b-ac24-a7d82b208355'	System	14 Oct 2020 01:50:40
User entered 'No (N)'	System	14 Oct 2020 01:50:40

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:50:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f24cf4ac-3318-451b-ac24-a7d82b208355'	System	14 Oct 2020 01:50:40
User entered '13 Oct 2020 21:50'	System	14 Oct 2020 01:50:40

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Oct 2020 14:57'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 2'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:18:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '44622ff5-6090-4329-8c39-42034595c755'	System	15 Oct 2020 05:19:26
User entered 'Yes (Y)'	System	15 Oct 2020 05:19:26

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:05', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '44622ff5-6090-4329-8c39-42034595c755'	System	15 Oct 2020 05:19:26
User entered '98.2'	System	15 Oct 2020 05:19:26



US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:09', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '44622ff5-6090-4329-8c39-42034595c755'	System	15 Oct 2020 05:19:26
User entered 'No (N)'	System	15 Oct 2020 05:19:26

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:19', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '44622ff5-6090-4329-8c39-42034595c755'	System	15 Oct 2020 05:19:26
User entered '15 Oct 2020 01:19'	System	15 Oct 2020 05:19:26

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 3'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:17', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8db46d92-9270-4bf0-a102-a99019109a11'	System	15 Oct 2020 22:41:39
User entered 'Yes (Y)'	System	15 Oct 2020 22:41:39

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:26', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8db46d92-9270-4bf0-a102-a99019109a11'	System	15 Oct 2020 22:41:39
User entered '98.5'	System	15 Oct 2020 22:41:39

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:29', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8db46d92-9270-4bf0-a102-a99019109a11'	System	15 Oct 2020 22:41:39
User entered 'No (N)'	System	15 Oct 2020 22:41:39



US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '8db46d92-9270-4bf0-a102-a99019109a11'	System	15 Oct 2020 22:41:39
User entered '15 Oct 2020 18:41'	System	15 Oct 2020 22:41:39

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 4'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '2ef564fb-b560-4122-a632-5f83fb1ed556'	System	16 Oct 2020 21:22:28
User entered 'Yes (Y)'	System	16 Oct 2020 21:22:28

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:19', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '2ef564fb-b560-4122-a632-5f83fb1ed556'	System	16 Oct 2020 21:22:28
User entered '98.3'	System	16 Oct 2020 21:22:28

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '2ef564fb-b560-4122-a632-5f83fb1ed556'	System	16 Oct 2020 21:22:28
User entered 'No (N)'	System	16 Oct 2020 21:22:28

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '2ef564fb-b560-4122-a632-5f83fb1ed556'	System	16 Oct 2020 21:22:28
User entered '16 Oct 2020 17:22'	System	16 Oct 2020 21:22:28



US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 5'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:26', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0c64c2ec-7c16-41df-adf6-f4145604ab90'	System	18 Oct 2020 05:18:43
User entered 'Yes (Y)'	System	18 Oct 2020 05:18:43

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0c64c2ec-7c16-41df-adf6-f4145604ab90'	System	18 Oct 2020 05:18:43
User entered '98.3'	System	18 Oct 2020 05:18:43

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0c64c2ec-7c16-41df-adf6-f4145604ab90'	System	18 Oct 2020 05:18:43
User entered 'No (N)'	System	18 Oct 2020 05:18:43

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0c64c2ec-7c16-41df-adf6-f4145604ab90'	System	18 Oct 2020 05:18:43
User entered '18 Oct 2020 01:18'	System	18 Oct 2020 05:18:43

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 6'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:00:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f85996d6-cdff-49f6-8e06-3b6c242dece5'	System	19 Oct 2020 04:01:16
User entered 'Yes (Y)'	System	19 Oct 2020 04:01:16

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f85996d6-cdff-49f6-8e06-3b6c242dece5'	System	19 Oct 2020 04:01:16
User entered '98.0'	System	19 Oct 2020 04:01:16

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:06', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f85996d6-cdff-49f6-8e06-3b6c242dece5'	System	19 Oct 2020 04:01:16
User entered 'No (N)'	System	19 Oct 2020 04:01:16

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:10', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f85996d6-cdff-49f6-8e06-3b6c242dece5'	System	19 Oct 2020 04:01:16
User entered '19 Oct 2020 00:01'	System	19 Oct 2020 04:01:16

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 7'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:28', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '19571973-cf46-48f7-b121-2aa6f5ee553b'	System	19 Oct 2020 21:52:47
User entered 'Yes (Y)'	System	19 Oct 2020 21:52:47

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '19571973-cf46-48f7-b121-2aa6f5ee553b'	System	19 Oct 2020 21:52:47
User entered '98.0'	System	19 Oct 2020 21:52:47

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '19571973-cf46-48f7-b121-2aa6f5ee553b'	System	19 Oct 2020 21:52:47
User entered 'No (N)'	System	19 Oct 2020 21:52:47

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:41', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '19571973-cf46-48f7-b121-2aa6f5ee553b'	System	19 Oct 2020 21:52:47
User entered '19 Oct 2020 17:52'	System	19 Oct 2020 21:52:47

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:31', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '38ee3a68-e548-4f53-843c-f2a6b685ee8a'	System	13 Oct 2020 15:46:57
User entered 'None (1)'	System	13 Oct 2020 15:46:57

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:34', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '38ee3a68-e548-4f53-843c-f2a6b685ee8a'	System	13 Oct 2020 15:46:57
User entered 'No (N)'	System	13 Oct 2020 15:46:57

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '38ee3a68-e548-4f53-843c-f2a6b685ee8a'	System	13 Oct 2020 15:46:57
User entered 'No (N)'	System	13 Oct 2020 15:46:57

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:39', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '38ee3a68-e548-4f53-843c-f2a6b685ee8a'	System	13 Oct 2020 15:46:57
User entered 'None (1)'	System	13 Oct 2020 15:46:57

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '38ee3a68-e548-4f53-843c-f2a6b685ee8a'	System	13 Oct 2020 15:46:57
User entered '13 Oct 2020 11:46'	System	13 Oct 2020 15:46:57

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Oct 2020 11:32'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Oct 2020 14:02'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'faaee05b-8ad2-4992-b35f-7c5e7a45e025'	System	14 Oct 2020 01:50:01
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 01:50:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:43', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'faaee05b-8ad2-4992-b35f-7c5e7a45e025'	System	14 Oct 2020 01:50:01
User entered 'No (N)'	System	14 Oct 2020 01:50:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:47', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'faaee05b-8ad2-4992-b35f-7c5e7a45e025'	System	14 Oct 2020 01:50:01
User entered 'No (N)'	System	14 Oct 2020 01:50:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'faaee05b-8ad2-4992-b35f-7c5e7a45e025'	System	14 Oct 2020 01:50:01
User entered 'None (1)'	System	14 Oct 2020 01:50:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'faaee05b-8ad2-4992-b35f-7c5e7a45e025'	System	14 Oct 2020 01:50:01
User entered '13 Oct 2020 21:49'	System	14 Oct 2020 01:50:01

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Oct 2020 14:57'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 2'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '6daaee94-8aab-4467-a1ea-5c3640912cc0'	System	15 Oct 2020 05:19:52
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 05:19:52

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:30', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '6daaee94-8aab-4467-a1ea-5c3640912cc0'	System	15 Oct 2020 05:19:52
User entered 'No (N)'	System	15 Oct 2020 05:19:52

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '6daaee94-8aab-4467-a1ea-5c3640912cc0'	System	15 Oct 2020 05:19:52
User entered 'No (N)'	System	15 Oct 2020 05:19:52

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:37', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '6daaee94-8aab-4467-a1ea-5c3640912cc0'	System	15 Oct 2020 05:19:52
User entered 'None (1)'	System	15 Oct 2020 05:19:52

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '6daaee94-8aab-4467-a1ea-5c3640912cc0'	System	15 Oct 2020 05:19:52
User entered '15 Oct 2020 01:19'	System	15 Oct 2020 05:19:52

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 3'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1004268f-6d1f-460b-85af-7a380fd474ef'	System	15 Oct 2020 22:42:03
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 22:42:03

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:47', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1004268f-6d1f-460b-85af-7a380fd474ef'	System	15 Oct 2020 22:42:03
User entered 'No (N)'	System	15 Oct 2020 22:42:03

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1004268f-6d1f-460b-85af-7a380fd474ef'	System	15 Oct 2020 22:42:03
User entered 'No (N)'	System	15 Oct 2020 22:42:03

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:52', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1004268f-6d1f-460b-85af-7a380fd474ef'	System	15 Oct 2020 22:42:03
User entered 'None (1)'	System	15 Oct 2020 22:42:03

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:41:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1004268f-6d1f-460b-85af-7a380fd474ef'	System	15 Oct 2020 22:42:03
User entered '15 Oct 2020 18:41'	System	15 Oct 2020 22:42:03

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 4'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7adb04e-e08d-49fa-8f99-f39e319be147'	System	16 Oct 2020 21:22:48
User entered 'None (1)'	System	16 Oct 2020 21:22:48

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:35', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7adb04e-e08d-49fa-8f99-f39e319be147'	System	16 Oct 2020 21:22:48
User entered 'No (N)'	System	16 Oct 2020 21:22:48

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:37', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7adb04e-e08d-49fa-8f99-f39e319be147'	System	16 Oct 2020 21:22:48
User entered 'No (N)'	System	16 Oct 2020 21:22:48

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7adb04e-e08d-49fa-8f99-f39e319be147'	System	16 Oct 2020 21:22:48
User entered 'None (1)'	System	16 Oct 2020 21:22:48

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7adb04e-e08d-49fa-8f99-f39e319be147'	System	16 Oct 2020 21:22:48
User entered '16 Oct 2020 17:22'	System	16 Oct 2020 21:22:48

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 5'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4c8c1ef4-211b-4c66-9e69-c76ee5388d53'	System	18 Oct 2020 05:19:01
User entered 'None (1)'	System	18 Oct 2020 05:19:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:48', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4c8c1ef4-211b-4c66-9e69-c76ee5388d53'	System	18 Oct 2020 05:19:01
User entered 'No (N)'	System	18 Oct 2020 05:19:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:50', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4c8c1ef4-211b-4c66-9e69-c76ee5388d53'	System	18 Oct 2020 05:19:01
User entered 'No (N)'	System	18 Oct 2020 05:19:01

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4c8c1ef4-211b-4c66-9e69-c76ee5388d53'	System	18 Oct 2020 05:19:01
User entered 'None (1)'	System	18 Oct 2020 05:19:01

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:18:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4c8c1ef4-211b-4c66-9e69-c76ee5388d53'	System	18 Oct 2020 05:19:01
User entered '18 Oct 2020 01:18'	System	18 Oct 2020 05:19:01

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 6'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:15', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e230fa24-455c-410e-938b-0db7baada42d'	System	19 Oct 2020 04:01:31
User entered 'None (1)'	System	19 Oct 2020 04:01:31

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:18', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e230fa24-455c-410e-938b-0db7baada42d'	System	19 Oct 2020 04:01:31
User entered 'No (N)'	System	19 Oct 2020 04:01:31

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e230fa24-455c-410e-938b-0db7baada42d'	System	19 Oct 2020 04:01:31
User entered 'No (N)'	System	19 Oct 2020 04:01:31

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e230fa24-455c-410e-938b-0db7baada42d'	System	19 Oct 2020 04:01:31
User entered 'None (1)'	System	19 Oct 2020 04:01:31

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e230fa24-455c-410e-938b-0db7baada42d'	System	19 Oct 2020 04:01:31
User entered '19 Oct 2020 00:01'	System	19 Oct 2020 04:01:31

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 7'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:46', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7f62f7c-8d9f-4c54-9770-49f0f51cc78a'	System	19 Oct 2020 21:53:06
User entered 'None (1)'	System	19 Oct 2020 21:53:06

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7f62f7c-8d9f-4c54-9770-49f0f51cc78a'	System	19 Oct 2020 21:53:06
User entered 'No (N)'	System	19 Oct 2020 21:53:06

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:51', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7f62f7c-8d9f-4c54-9770-49f0f51cc78a'	System	19 Oct 2020 21:53:06
User entered 'No (N)'	System	19 Oct 2020 21:53:06

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7f62f7c-8d9f-4c54-9770-49f0f51cc78a'	System	19 Oct 2020 21:53:06
User entered 'None (1)'	System	19 Oct 2020 21:53:06

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:52:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'e7f62f7c-8d9f-4c54-9770-49f0f51cc78a'	System	19 Oct 2020 21:53:06
User entered '19 Oct 2020 17:52'	System	19 Oct 2020 21:53:06

US3802218

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:51', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:56', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:46:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:47:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'None (0)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:47:04', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered 'No (N)'	System	13 Oct 2020 15:47:12

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T11:47:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'db1540b6-ea72-4067-9e43-a74e6370d4db'	System	13 Oct 2020 15:47:12
User entered '13 Oct 2020 11:47'	System	13 Oct 2020 15:47:12



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Oct 2020 11:32'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Oct 2020 14:02'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:48:54', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:48:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37



**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:49:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:10', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'None (0)'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:14', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered 'No (N)'	System	14 Oct 2020 01:49:37

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-13T21:49:21', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '1cf10a93-8271-4d5e-b6f1-793c80818f9a'	System	14 Oct 2020 01:49:37
User entered '13 Oct 2020 21:49'	System	14 Oct 2020 01:49:37

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '13 Oct 2020 14:57'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 2'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:54', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:19:58', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:05', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'None (0)'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered 'No (N)'	System	15 Oct 2020 05:20:28

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T01:20:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '7ad2a0b5-7669-4e7e-8ae9-3c054e407ba0'	System	15 Oct 2020 05:20:28
User entered '15 Oct 2020 01:20'	System	15 Oct 2020 05:20:28

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:16:41



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 3'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'None (0)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:17', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'No interference with activity (1)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'None (0)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:22', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'None (0)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:24', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'None (0)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:27', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'None (0)'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered 'No (N)'	System	16 Oct 2020 19:24:32



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-15T18:42:38', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f7bed483-a88f-4499-abe8-fa77447fb8e4'	System	16 Oct 2020 19:24:32
User entered '15 Oct 2020 18:42'	System	16 Oct 2020 19:24:32

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 4'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:51', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:53', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:22:59', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'None (0)'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:23:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered 'No (N)'	System	16 Oct 2020 21:23:10

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-16T17:23:07', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '54c2ab99-30ff-437e-99ea-40f3a354e0a9'	System	16 Oct 2020 21:23:10
User entered '16 Oct 2020 17:23'	System	16 Oct 2020 21:23:10

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 5'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:04', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:07', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:10', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:12', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'None (0)'	System	18 Oct 2020 05:19:30

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:15', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered 'No (N)'	System	18 Oct 2020 05:19:30

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-18T01:19:20', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0a903c1f-c779-499a-92eb-1ed96d3480d8'	System	18 Oct 2020 05:19:30
User entered '18 Oct 2020 01:19'	System	18 Oct 2020 05:19:30

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:16:41



**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 6'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:31', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:38', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:41', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:43', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:45', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'None (0)'	System	19 Oct 2020 04:01:58



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered 'No (N)'	System	19 Oct 2020 04:01:58

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T00:01:54', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '4d40998b-ef02-4065-b278-c7bdb928772f'	System	19 Oct 2020 04:01:58
User entered '19 Oct 2020 00:01'	System	19 Oct 2020 04:01:58

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:49:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	13 Oct 2020 15:16:41
User entered 'Day 7'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:05', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:08', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27



US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:10', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:11', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:13', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'None (0)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:17', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered 'No (N)'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-10-19T17:53:23', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'afb2e1a0-1682-42b1-a4f6-49c0a3bc2977'	System	19 Oct 2020 21:53:27
User entered '19 Oct 2020 17:53'	System	19 Oct 2020 21:53:27

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:16:41

US3802218

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:49:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:16:41

**US3802218**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Melissa Andrasko (b) (4) (b) (4)	22 Oct 2020 18:55:44



**US3802218**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '22 Oct 2020'	(b) (4) Melissa Andrasko (b) (4) (b) (4)	22 Oct 2020 18:55:44

US3802218

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Contact Not Made (CONTACT NOT MADE)'	Melissa Andrasko (b) (4) (b) (4)	22 Oct 2020 18:55:44

US3802218

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Contact attempted on 10/20,10/21,10/22.'	(b) (4) Melissa Andrasko (b) (4) (b) (4)	22 Oct 2020 18:55:44

**US3802218**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Melissa Andrasko (b) (4)	22 Oct 2020 18:55:50

**US3802218**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'I'	System	22 Oct 2020 18:55:50

**US3802218**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Melissa Andrasko (b) (4)	28 Oct 2020 15:10:20

US3802218

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 09:04:20
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'updated' (Site from System).	Melissa Andrasko (b) (4) (b) (4)	28 Oct 2020 15:14:11
User entered '26 Oct 2020' reason for change: Data Entry Error	Melissa Andrasko (b) (4) (b) (4)	28 Oct 2020 15:13:32
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Oct 2020 15:10:20
User entered '23 Oct 2020'	Melissa Andrasko (b) (4) (b) (4)	28 Oct 2020 15:10:20

US3802218

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'Contact Not Made (CONTACT NOT MADE)'	Melissa Andrasko (b) (4) (b) (4)	28 Oct 2020 15:10:20



US3802218

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Attempted to contact participant 3 times without success'	(b) (4) Melissa Andrasko (b) (4)	28 Oct 2020 15:10:20

US3802218

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Melissa Andrasko (b) (4) (b) (4)	28 Oct 2020 15:14:31

**US3802218**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'I'	System	28 Oct 2020 15:14:31

**US3802218**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	05 Nov 2020 18:33:34

**US3802218**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '6 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	06 Nov 2020 20:26:39
User entered '5 Nov 2020'	(b) (4)	
	Lalicia Roman (b) (4)	05 Nov 2020 18:33:34
	(b) (4)	

US3802218

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Jennifer Nagg (b) (4)	06 Nov 2020 20:26:39
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Lalicia Roman (b) (4)	05 Nov 2020 18:33:34
	(b) (4)	

US3802218

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	06 Nov 2020 20:26:39
	(b) (4)	
User entered 'contact attempted 3x'	Lalicia Roman (b) (4)	05 Nov 2020 18:33:34
	(b) (4)	

US3802218

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	05 Nov 2020 18:33:39



**US3802218**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'I'	System	05 Nov 2020 18:33:39

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:23

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '12 Nov 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:23

US3802218

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

[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 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Clinic (Clinic)'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:23

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'VISIT3'	System	12 Nov 2020 15:58:23

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '12 Nov 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered '10:10'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48



**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '12 Nov 2020 10:10'	System	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '97.3' F	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Infrared'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '89'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'bpm'	System	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User closed query '	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:15
Per CDM: Respiratory rate >16 and ≤20 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate. ' (Site from DM). Query '		
	Dominic Kramer (b) (4) (b) (4)	24 Nov 2020 16:17:37
Per CDM: Respiratory rate >16 and ≤20 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate. ' answered with 'Value is in Range. NCS' (Site from DM). User opened query '		
	(b) (4), (b) (6)	24 Nov 2020 12:17:04
Per CDM: Respiratory rate >16 and ≤20 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate. ' (Site from DM). User entered '18'		
	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'breaths/min'	System	12 Nov 2020 15:58:48



US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User closed query 'Per CDM: Systolic Blood Pressure >150 and ≤155 per CCG v2.0 considered grade 2. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:52
Query 'Per CDM: Systolic Blood Pressure >150 and ≤155 per CCG v2.0 considered grade 2. Please indicate if CS/NCS and report as AE, if appropriate' answered with 'Hypertension reported in med history. NCS' (Site from DM).	Dominic Kramer (b) (4) (b) (4)	24 Nov 2020 16:18:18
User opened query 'Per CDM: Systolic Blood Pressure >150 and ≤155 per CCG v2.0 considered grade 2. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:17:28
User entered '154'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'mmHg'	System	12 Nov 2020 15:58:48

US3802218

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '88'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:48

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'mmHg'	System	12 Nov 2020 15:58:48

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17

US3802218

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:53

US3802218

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:58:53



**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	12 Nov 2020 15:59:02

US3802218

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '12 Nov 2020'	(b) (4) Emily Carney (b) (4)	12 Nov 2020 15:59:02
	(b) (4)	

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '10:51'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Nov 2020 15:59:02

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered '12 Nov 2020 10:51'	System	12 Nov 2020 15:59:02

US3802218

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	12 Nov 2020 15:59:05

**US3802218**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'I'	System	12 Nov 2020 15:59:05

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 64'	System	11 Sep 2020 14:49:41

US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

[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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-11-12T18:28:55', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '67c68bb4-ae32-4f06-b894-0a7d322ea96e'	System	12 Nov 2020 23:29:17
User entered 'No (N)'	System	12 Nov 2020 23:29:17



US3802218

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:22

Have you been exposed to someone with 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)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-11-12T18:29:02', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '67c68bb4-ae32-4f06-b894-0a7d322ea96e'	System	12 Nov 2020 23:29:17
User entered 'No (N)'	System	12 Nov 2020 23:29:17

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-11-12T18:29:12', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '67c68bb4-ae32-4f06-b894-0a7d322ea96e'	System	12 Nov 2020 23:29:17
User entered '12 Nov 2020 18:29:12'	System	12 Nov 2020 23:29:17

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 14:49:41

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:25:54
Data entry locked.	System	11 Sep 2020 14:49:41
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 14:49:41

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29
Data entry locked.	System	11 Sep 2020 14:49:41
User entered 'Day 71'	System	11 Sep 2020 14:49:41

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[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)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Have you been exposed to someone with 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)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29
Data entry locked.	System	11 Sep 2020 14:49:41
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 14:49:41

**US3802218**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:33:29
Data entry locked.	System	11 Sep 2020 14:49:41
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 14:49:41



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[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 (390c60986467e739)', Time: '2020-11-23T23:56:42', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0b3ec151-17d1-46e4-9a07-c32c0e35db10'	System	24 Nov 2020 04:56:59
User entered 'No (N)'	System	24 Nov 2020 04:56:59

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Have you been exposed to someone with 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 (390c60986467e739)', Time: '2020-11-23T23:56:49', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0b3ec151-17d1-46e4-9a07-c32c0e35db10'	System	24 Nov 2020 04:56:59
User entered 'No (N)'	System	24 Nov 2020 04:56:59

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-11-23T23:56:54', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '0b3ec151-17d1-46e4-9a07-c32c0e35db10'	System	24 Nov 2020 04:56:59
User entered '23 Nov 2020 23:56:54'	System	24 Nov 2020 04:56:59

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[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 (390c60986467e739)', Time: '2020-12-02T04:04:32', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '93f47aa0-67b0-4cbd-b791-0690407b853a'	System	02 Dec 2020 09:04:46
User entered 'No (N)'	System	02 Dec 2020 09:04:46



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

Have you been exposed to someone with 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 (390c60986467e739)', Time: '2020-12-02T04:04:36', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '93f47aa0-67b0-4cbd-b791-0690407b853a'	System	02 Dec 2020 09:04:46
User entered 'No (N)'	System	02 Dec 2020 09:04:46

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-12-02T04:04:40', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '93f47aa0-67b0-4cbd-b791-0690407b853a' User entered '02 Dec 2020 04:04:40'	System	02 Dec 2020 09:04:46

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[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 (390c60986467e739)', Time: '2020-12-06T04:11:57', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '82bcd859-e69a-4625-ae84-1ae990e61e90'	System	06 Dec 2020 09:12:07
User entered 'No (N)'	System	06 Dec 2020 09:12:07

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

Have you been exposed to someone with 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 (390c60986467e739)', Time: '2020-12-06T04:12:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '82bcd859-e69a-4625-ae84-1ae990e61e90'	System	06 Dec 2020 09:12:07
User entered 'No (N)'	System	06 Dec 2020 09:12:07

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-12-06T04:12:03', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '82bcd859-e69a-4625-ae84-1ae990e61e90'	System	06 Dec 2020 09:12:07
User entered '06 Dec 2020 04:12:03'	System	06 Dec 2020 09:12:07



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[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 (390c60986467e739)', Time: '2020-12-15T17:37:30', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '87ccd3c8-06d8-46d8-a816-9f58fd4dc1ce'	System	15 Dec 2020 22:38:08
User entered 'No (N)'	System	15 Dec 2020 22:38:08

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Have you been exposed to someone with 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 (390c60986467e739)', Time: '2020-12-15T17:37:33', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '87ccd3c8-06d8-46d8-a816-9f58fd4dc1ce'	System	15 Dec 2020 22:38:08
User entered 'No (N)'	System	15 Dec 2020 22:38:08

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (390c60986467e739)', Time: '2020-12-15T17:37:44', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '87ccd3c8-06d8-46d8-a816-9f58fd4dc1ce'	System	15 Dec 2020 22:38:08
User entered '15 Dec 2020 17:37:44'	System	15 Dec 2020 22:38:08

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[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 (abb02f9f5ca0c90f)', Time: '2021-04-12T11:57:39-04:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '85b03250-76b2-40b0-90d6-a50ec8948722'	System	12 Apr 2021 15:58:54
User entered 'No (N)'	System	12 Apr 2021 15:58:54

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

Have you been exposed to someone with 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 (abb02f9f5ca0c90f)', Time: '2021-04-12T11:57:43-04:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '85b03250-76b2-40b0-90d6-a50ec8948722'	System	12 Apr 2021 15:58:54
User entered 'No (N)'	System	12 Apr 2021 15:58:54

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (abb02f9f5ca0c90f)', Time: '2021-04-12T11:57:50-04:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '85b03250-76b2-40b0-90d6-a50ec8948722'	System	12 Apr 2021 15:58:54
User entered '12 Apr 2021 11:57:50'	System	12 Apr 2021 15:58:54

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[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 (abb02f9f5ca0c90f)', Time: '2021-04-18T16:47:55-04:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '841fa64f-af56-4cdd-95f1-2dadaa5483e4' User entered 'No (N)'	System	18 Apr 2021 21:37:37
	System	18 Apr 2021 21:37:37



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

Have you been exposed to someone with 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 (abb02f9f5ca0c90f)', Time: '2021-04-18T16:47:59-04:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '841fa64f-af56-4cdd-95f1-2dadaa5483e4'	System	18 Apr 2021 21:37:37
User entered 'No (N)'	System	18 Apr 2021 21:37:37

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (abb02f9f5ca0c90f)', Time: '2021-04-18T16:48:05-04:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: '841fa64f-af56-4cdd-95f1-2dadaa5483e4'	System	18 Apr 2021 21:37:37
User entered '18 Apr 2021 16:48:05'	System	18 Apr 2021 21:37:37

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:33:29



**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:33:29

**US3802218**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:49:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:33:29
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:33:29

US3802218

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:49:22**

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)	30 Apr 2021 22:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (abb02f9f5ca0c90f)', Time: '2021-04-12T11:58:00-04:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f06290c2-27dd-487e-a435-8cb97524e8e9'	System	12 Apr 2021 15:58:56
User entered 'No (N)'	System	12 Apr 2021 15:58:56

**US3802218**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (abb02f9f5ca0c90f)', Time: '2021-04-12T11:58:06-04:00', User OID: 'PatientReportedOutcome (US3802218)', ODM File OID: 'f06290c2-27dd-487e-a435-8cb97524e8e9'	System	12 Apr 2021 15:58:56
User entered '12 Apr 2021 11:58:06'	System	12 Apr 2021 15:58:56

**US3802218**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	10 Dec 2020 13:29:10

**US3802218**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '8 Dec 2020'	(b) (4) Jamie Fries (b) (4) (b) (4)	10 Dec 2020 13:29:10

US3802218

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Fries (b) (4) (b) (4)	10 Dec 2020 13:29:10

US3802218

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	Jamie Fries (b) (4)	10 Dec 2020 13:29:10



**US3802218**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	10 Dec 2020 13:29:13

**US3802218**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:21:17
User entered 'I'	System	10 Dec 2020 13:29:13

**US3802218**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	12 Jan 2021 15:14:22

**US3802218**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '19 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Emily Dougherty (b) (4)	19 Jan 2021 17:51:43
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Emily Carney (b) (4)	13 Jan 2021 16:00:14
User entered '12 Jan 2021'	(b) (4)	
	Emily Carney (b) (4)	12 Jan 2021 15:14:22
	(b) (4)	

US3802218

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Emily Dougherty (b) (4)	19 Jan 2021 17:51:49
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Emily Carney (b) (4)	12 Jan 2021 15:14:22
	(b) (4)	

US3802218

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'ATTEMPTED THREE TIMES. MAILBOX FULL. Participant called outside of window' reason for change: Data Entry Error	(b) (4) Emily Dougherty (b) (4)	19 Jan 2021 17:51:43
User entered 'Attempted three times. Mailbox full.' reason for change: Data Entry Error	Emily Carney (b) (4)	13 Jan 2021 16:00:14
User entered 'Number was deactivated. Will email.'	(b) (4) Emily Carney (b) (4)	12 Jan 2021 15:14:22

US3802218

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	12 Jan 2021 15:14:37

**US3802218**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User entered '1'	System	12 Jan 2021 15:14:37



**US3802218**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	12 Feb 2021 20:09:55

**US3802218**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered '11 Feb 2021'	(b) (4) Emily Carney (b) (4)	12 Feb 2021 20:09:55

US3802218

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4)	12 Feb 2021 20:09:55

US3802218

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered empty.	(b) (4) Emily Carney (b) (4)	12 Feb 2021 20:09:55

US3802218

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	12 Feb 2021 20:09:47

**US3802218**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User entered '1'	System	12 Feb 2021 20:09:47

**US3802218**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	16 Mar 2021 15:39:14
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	15 Mar 2021 15:10:08

**US3802218**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	16 Mar 2021 15:39:14
User entered '12 Mar 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	15 Mar 2021 15:10:08



**US3802218**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	16 Mar 2021 15:39:14
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Emily Carney (b) (4)	15 Mar 2021 15:10:08

**US3802218**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:49:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	16 Mar 2021 15:39:14
User entered 'Attempted to call twice and emailed once.'	(b) (4) Emily Carney (b) (4)	15 Mar 2021 15:10:08

US3802218

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User signature succeeded.	Judith Martin (b) (4)	16 Mar 2021 15:39:14
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	15 Mar 2021 15:10:14

**US3802218**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:11:07
User entered 'I'	System	15 Mar 2021 15:10:14

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered 'Yes (Y)'	Lisa Vavro (b) (4)	12 Apr 2021 14:51:29
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered '12 Apr 2021'	Lisa Vavro (b) (4)	12 Apr 2021 14:51:29
	(b) (4)	

US3802218

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
User entered 'Clinic (Clinic)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	12 Apr 2021 14:51:29

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	12 Apr 2021 14:51:29



US3802218

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered 'No (N)'	Lisa Vavro (b) (4)	12 Apr 2021 14:51:41
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered empty.	Lisa Vavro (b) (4)	12 Apr 2021 14:51:41
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered empty.	Lisa Vavro (b) (4)	12 Apr 2021 14:51:41
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 14:51:41

US3802218

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered empty.	Lisa Vavro (b) (4)	12 Apr 2021 14:51:41
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered empty.	Lisa Vavro (b) (4)	12 Apr 2021 14:51:41
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered empty.	Lisa Vavro (b) (4)	12 Apr 2021 14:51:41
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered empty.	Lisa Vavro (b) (4)	12 Apr 2021 14:51:41
	(b) (4)	



**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 14:51:41

US3802218

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered empty.	Lisa Vavro (b) (4)	12 Apr 2021 14:51:41
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 14:51:41

US3802218

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered empty.	Lisa Vavro (b) (4)	12 Apr 2021 14:51:41
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 14:51:41

US3802218

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered empty.	Lisa Vavro (b) (4)	12 Apr 2021 14:51:41
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:49:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 14:51:41

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:49:22**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered 'No (N)'	Lisa Vavro (b) (4)	12 Apr 2021 14:51:47
	(b) (4)	



US3802218

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered empty.	Lisa Vavro (b) (4)	12 Apr 2021 14:51:47
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered 'Yes (Y)'	Lisa Vavro (b) (4)	12 Apr 2021 14:52:00
	(b) (4)	

US3802218

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered '12 Apr 2021'	Lisa Vavro (b) (4)	12 Apr 2021 14:52:00
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered '10:23'	Lisa Vavro (b) (4)	12 Apr 2021 14:52:00
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 10:23'	System	12 Apr 2021 14:52:00

US3802218

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	12 Apr 2021 19:22:41
	(b) (4)	
User entered 'Yes (Y)'	Lisa Vavro (b) (4)	12 Apr 2021 14:52:05
	(b) (4)	

**US3802218**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 14:52:05

US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:45:17



US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered '11 Feb 2021'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:45:17

US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:22

[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 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:45:17

**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:49:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User entered 'UNBLND_DECIDE'	System	11 Feb 2021 16:45:17

US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:49:22

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered '11 Feb 2021'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:46:10

**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:49:22**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:54:12
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:11:17

**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:49:22**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:46:10

**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:49:22**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:54:12
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:11:17

US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:49:22

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered '11 Feb 2021'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:46:10



US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:49:22

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:46:10

US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:49:22

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:46:10

**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:49:22**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:46:10

US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:49:22

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:46:10

**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:49:22**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User entered empty.	System	11 Feb 2021 16:46:10

**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:49:22**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User entered empty.	System	11 Feb 2021 16:46:10

US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:46:30

US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered '11 Feb 2021'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:46:30



**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered '11:21'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:46:30

**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:49:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User entered '11 Feb 2021 11:21'	System	11 Feb 2021 16:46:30

US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:49:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:48:30

US3802218

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:49:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered '11 Feb 2021'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:48:30

**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:49:22**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:37:24
User entered '11:24'	(b) (4) Lalicia Roman (b) (4)	11 Feb 2021 16:48:30

**US3802218**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:49:22**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:44:19
User entered '11 Feb 2021 11:24'	System	11 Feb 2021 16:48:30

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:49:22**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:24
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:18:08
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:07:24

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:23:46
Reviewed for Safety.		03 Nov 2020 17:23:40
User entered		03 Nov 2020 17:23:09
'USA-US098-2020-mRNA-1273-P301000001'		
User entered 'New'		03 Nov 2020 17:23:09



US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
Query 'PV Query: Was this event considered a worsening of the subjects medical history paraoesophageal hernia. If so, please consider updating the event tern to reflect the worsening of paraoesophageal hiatal hernia. If not please explain.' canceled (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:12:49
	(b) (4), (b) (6)	18 Nov 2020 16:00:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Paraesophageal hiatal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 22:06:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 22:06:48
Data point term sent to Coder	System	15 Nov 2020 13:05:04
DataPoint Un-verified.	Jennifer Nagg (b) (4) (b) (4)	15 Nov 2020 13:04:37
Coding entries removed.	Jennifer Nagg (b) (4) (b) (4)	15 Nov 2020 13:04:37
User entered 'PARAESOPHOGEAL HIATAL HERNIA worsening' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	15 Nov 2020 13:04:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Paraesophageal hiatal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:50:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:50:39
User opened query 'PV Query: Was this event considered a worsening of the subjects medical history paraoesophageal hernia. If so, please consider updating the event tern to reflect the worsening of paraoesophageal hiatal hernia. If not please explain.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 13:42:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:09:51

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Nov 2020 13:27:06
User closed query 'CDM coding: Kindly update the term if it means 'Paraesophageal hiatal hernia', else please clarify' (Site from System).	System	11 Nov 2020 13:26:47
Query 'CDM coding: Kindly update the term if it means 'Paraesophageal hiatal hernia', else please clarify' answered with 'updated' (Site from System).	Lalicia Roman (b) (4)	11 Nov 2020 13:26:47
DataPoint Un-verified.	(b) (4)	
	Lalicia Roman (b) (4)	11 Nov 2020 13:26:17
	(b) (4)	
User entered 'PARAESOPHOGEAL Hiatal hernia' reason for change: Data Entry Error	Lalicia Roman (b) (4)	11 Nov 2020 13:26:17
	(b) (4)	
User opened query 'CDM coding: Kindly update the term if it means 'Paraesophageal hiatal hernia', else please clarify' (Site from System).	Coder Import (b) (4)	11 Nov 2020 06:18:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:08:29
DataPoint Un-verified.		10 Nov 2020 15:05:53
DataPoint Verified.		03 Nov 2020 16:20:10
Data point term sent to Coder	System	02 Nov 2020 21:09:56
User entered 'Hernia, paraesophageal repair'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:20:14
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:20:16
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:20:18
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
User closed query 'PV Query: It was reported since Sept 2020 the subject was experiencing worsening symptoms including postprandial epigastric pain and dysphagia. Please consider updating the start date of the event to when the signs and symptoms started.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 18:11:24
Query 'PV Query: It was reported since Sept 2020 the subject was experiencing worsening symptoms including postprandial epigastric pain and dysphagia. Please consider updating the start date of the event to when the signs and symptoms started.' answered with 'This specific even started OCT 28 2020. On this day pts hialal hernia got worse that caused him to be hospitalized' (Site from Safety).	Jamie Fries (b) (4) (b) (4)	18 Dec 2020 20:02:47
User opened query 'PV Query: It was reported since Sept 2020 the subject was experiencing worsening symptoms including postprandial epigastric pain and dysphagia. Please consider updating the start date of the event to when the signs and symptoms started.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:14:14
User closed query 'PV Query: It was reported since Sept 2020 the subject was experiencing worsening symptoms including postprandial epigastric pain and dysphagia. Please consider updating the start date of the event to when the signs and symptoms started.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:54:42
Query 'PV Query: It was reported since Sept 2020 the subject was experiencing worsening symptoms including postprandial epigastric pain and dysphagia. Please consider updating the start date of the event to when the signs and symptoms started.' answered with 'this was a scheduled surgery' (Site from Safety).	Jennifer Nagg (b) (4) (b) (4)	15 Nov 2020 13:02:33
User opened query 'PV Query: It was reported since Sept 2020 the subject was experiencing worsening symptoms including postprandial epigastric pain and dysphagia. Please consider updating the start date of the event to when the signs and symptoms started.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 13:42:58

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:21
User entered '28 Oct 2020'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:36:19
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08



**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:09:03
DataPoint Un-verified.	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 13:26:17
User entered 'No (N)' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 13:26:17
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:25
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:09:05
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Nov 2020 13:26:39
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	11 Nov 2020 13:26:39
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Nov 2020 13:26:17
DataPoint Un-verified.	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 13:26:17
User entered '5 Nov 2020' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 13:26:17
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:20:33
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:20:35
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
User closed query 'Grade not recorded in SAE event form. please confirm source of this data . ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:09:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:09:17
Query 'Grade not recorded in SAE event form. please confirm source of this data . ' answered with 'Recorded on form' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 01:00:46
User opened query 'Grade not recorded in SAE event form. please confirm source of this data . ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 16:28:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:20:43
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:21:12
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08



**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:21:15
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
User closed query 'Per CDM: Thanks for updating information Kindly update Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 08:40:10
Query 'Per CDM: Thanks for updating information Kindly update Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile. Thank you!' answered with 'done' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 20:51:21
User opened query 'Per CDM: Thanks for updating information Kindly update Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:52:17
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		09 Nov 2020 09:51:16
DataPoint Verified.		03 Nov 2020 16:21:31
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospital admission date is recorded, subject is still hospitalized' (Site from System).	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:11:07
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	02 Nov 2020 21:09:08
User entered 'I'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:21:29
User entered '28 Oct 2020'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:09:30
DataPoint Un-verified.	Jennifer Nagg (b) (4)	10 Nov 2020 20:51:12
User entered '5 Nov 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Jennifer Nagg (b) (4)	10 Nov 2020 20:51:12
	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:21:35
User entered empty.	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:21:36
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:21:38
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:21:42
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:21:44
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08



US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:21:46
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:21:49
User entered 'Not Related (NOT RELATED)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:21:51
User entered 'Not Related (NOT RELATED)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
Query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with study drug from none to not applicable.' canceled (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:13:40
	(b) (4), (b) (6)	18 Nov 2020 15:49:21
DataPoint Un-verified.	Jennifer Nagg (b) (4)	15 Nov 2020 13:04:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	15 Nov 2020 13:04:37
User opened query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with study drug from none to not applicable.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:40:38
		03 Nov 2020 16:21:53
User entered 'None (NONE)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

None

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
	(b) (4)	
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		18 Feb 2021 20:13:09
User entered '0' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	18 Feb 2021 20:13:09
	(b) (4)	
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	18 Feb 2021 20:11:58
DataPoint Un-verified.	Jennifer Nagg (b) (4)	18 Feb 2021 20:11:58
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	18 Feb 2021 20:11:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:55
User entered '0'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08
	(b) (4)	

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

Concomitant Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: RQ: Response noted, however, please update the CM's indication to include this AE. Reconcile as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 04:40:47
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
Query 'Per DM CLR: RQ: Response noted, however, please update the CM's indication to include this AE. Reconcile as appropriate. Otherwise, clarify.' answered with 'none reported' (Site from DM).	Jennifer Nagg (b) (4)	18 Feb 2021 20:12:50
DataPoint Un-verified.	Jennifer Nagg (b) (4)	18 Feb 2021 20:11:58
User entered '0' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	18 Feb 2021 20:11:58
User opened query 'Per DM CLR: RQ: Response noted, however, please update the CM's indication to include this AE. Reconcile as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 11:54:28
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 20:18:04
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'heparin recorded on con med form' (Site from DM).	Jennifer Nagg (b) (4)	19 Jan 2021 12:38:51
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:21:59
User entered '1'	Jennifer Nagg (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. Please note, if the corresponding procedure was performed for the Medical History condition, please update to uncheck or unselect Other Action Taken of Concomitant Procedure. Otherwise, update Indication of the corresponding procedure to AE so data would match.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:28:21
Query 'Per DM CLR - RQ: Site's response noted. Please note, if the corresponding procedure was performed for the Medical History condition, please update to uncheck or unselect Other Action Taken of Concomitant Procedure. Otherwise, update Indication of the corresponding procedure to AE so data would match.' answered with 'The con procedure has been updated to AE since it was the worsening of the hernia that caused the need for the surgery. This all now matches appropriately.' (Site from DM).	Emily Carney (b) (4) (b) (4)	31 Mar 2021 16:16:24
User opened query 'Per DM CLR - RQ: Site's response noted. Please note, if the corresponding procedure was performed for the Medical History condition, please update to uncheck or unselect Other Action Taken of Concomitant Procedure. Otherwise, update Indication of the corresponding procedure to AE so data would match.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 11:49:44
User signature succeeded.	Judith Martin (b) (4) (b) (4)	19 Feb 2021 14:48:31
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 20:18:07
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'it started as medical history and then developed AE when surgery was needed to repair hernia' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	19 Jan 2021 12:40:11

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Dec 2020 00:22:31
	(b) (4), (b) (6)	03 Nov 2020 16:22:01
User entered 'I'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08



US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:09:36
DataPoint Un-verified.	Lalicia Roman (b) (4)	11 Nov 2020 13:26:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 13:26:39
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:22:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:35:48
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
Query 'PV Query: Discharge summary was not received. Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. Please leave query open until information has been sent.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:06:11
User opened query 'PV Query: Discharge summary was not received. Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. Please leave query open until information has been sent.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 22:21:07
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 21:16:28
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 21:07:04
User closed query 'Per DM CLR: SAE Narrative = LEFT PIGTAIL CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 20:18:26
User closed query 'Per DM CLR: SAE Narrative = CXR 10/31/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 20:18:24
User closed query 'Per DM CLR: SAE Narrative = CXR 10/28/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 20:18:21

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' answered with 'faxed 1/20/2021 1048' (Site from Safety).	Melissa Andrasko (b) (4) (b) (4)	20 Jan 2021 15:48:43
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'not done' (Site from Safety).	Jennifer Nagg (b) (4) (b) (4)	19 Jan 2021 12:51:16
Query 'Per DM CLR: SAE Narrative = CXR 10/31/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	19 Jan 2021 12:46:57
Query 'Per DM CLR: SAE Narrative = CXR 10/28/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	19 Jan 2021 12:46:52
Query 'Per DM CLR: SAE Narrative = LEFT PIGTAIL CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added ' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	19 Jan 2021 12:45:32
User opened query 'Per DM CLR: SAE Narrative = LEFT PIGTAIL CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 00:22:09
User opened query 'Per DM CLR: SAE Narrative = CXR 10/31/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		28 Dec 2020 00:22:03
User opened query 'Per DM CLR: SAE Narrative = CXR 10/28/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		28 Dec 2020 00:21:55

US3802218

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:22

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety). User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:43:12  12 Nov 2020 13:41:08  03 Nov 2020 16:35:44
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Nov 2020 21:12:04
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Nov 2020 21:12:04
User entered '10/28/2020-Admitted prior to surgery-Past medical history report of known paraesophageal hernia that has been experiencing worsening symptoms. Admitted for a laparoscopic repair of hernia. CXR: cardiomediastinal silhouette not enlarged, including hiatal hernia, Pulmonary vascular markings not enlarged, lung volumes normal, no focal consolidation, pleural effusion or significant pneumothorax. No acute osseous or soft tissue abnormalities 10/29/2020- VS 37.0, 97/62, 76, 16, 93%, 108kg, 34.9BMI 10/30/2020- Repair hiatal hernia laproscopic, esophogoscopy, gastropexy, estimated blood loss 10ml, findings: giant paraesophageal hernia with majority of stomach intrathoracic lap GPEH repair with gastropexy, hiatal closure with 2 posterior stitches and 3 stitches at 3:00, left pigtail. VS 36.6, 115/60, 84, 16, 97% 10/31/2020- no acute events overnight, adequate pain control. CXR: small amount of left subpulmonic effusion left pigtail catheter remains in place. 11/1/2020- VS 37.5, 84/52, 64, 17, 95%, continue inpatient care' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:12:04

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1692 of 2079

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Nov 2020 21:09:08
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	02 Nov 2020 21:09:08

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Nov 2020 21:09:08

**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Nov 2020 21:09:08



**US3802218**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Nov 2020 21:09:08

US3802218

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:49:22**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:24
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:36:46
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:51:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE, PRODUCTSYNONYM: TRIUMEQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 12:43:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 12:43:42
User signature succeeded.	Judith Martin (b) (4) (b) (4)	19 Feb 2021 14:48:31
Data point term sent to Coder	System	18 Feb 2021 18:59:13
DataPoint Un-verified.	Jennifer Nagg (b) (4) (b) (4)	18 Feb 2021 18:59:11
Coding entries removed.	Jennifer Nagg (b) (4) (b) (4)	18 Feb 2021 18:59:11
User entered 'TRIUMEQ 600mg/50mg/300mg' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	18 Feb 2021 18:59:11
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:14:45
User closed query 'Please update Medication name to Triumeq' (Site from CRA).		10 Nov 2020 04:29:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE, PRODUCTSYNONYM: TRIUMEQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:48:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:48:28
Data point term sent to Coder	System	04 Nov 2020 01:47:29
Query 'Please update Medication name to Triumeq' answered with 'Done' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:46:49

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1698 of 2079

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

Name of Medication

Audit	User	Time (GMT)
Coding entries removed.	Jennifer Nagg (b) (4)	04 Nov 2020 01:46:42
User entered 'TRIUmeq' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	04 Nov 2020 01:46:42
User opened query 'Please update Medication name to 'Triumeq' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 16:42:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE, PRODUCTSYNONYM: TRIUMEQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 10:25:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 10:25:55
Data point term sent to Coder	System	11 Sep 2020 14:52:53
User entered 'Triameq'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:42:22
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:42:34
User entered 'HIV'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Since this Con med is a combination drug, the Dose per administration should be recorded as "600/50/300", "Dose unit=mg" as per the CRF completion guidelines. Kindly update the data as appropriate. Thankyou.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	04 Mar 2021 15:19:51
Query 'Per CDM: Since this Con med is a combination drug, the Dose per administration should be recorded as "600/50/300", "Dose unit=mg" as per the CRF completion guidelines. Kindly update the data as appropriate. Thankyou.' answered with 'Have updated as asked. Thank you.' (Site from DM). Signature has been broken.	Judith Martin (b) (4) (b) (4) (b) (4), (b) (6)	03 Mar 2021 16:36:38 23 Feb 2021 20:12:30
User entered '600/50/300' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 20:12:04
User opened query 'Per CDM: Since this Con med is a combination drug, the Dose per administration should be recorded as "600/50/300", "Dose unit=mg" as per the CRF completion guidelines. Kindly update the data as appropriate. Thankyou.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:47:57
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include all of the components (e.g. Medication Name = TRIUMEQ 600mg/50mg/300mg) and specify the # of tabs per eCRF completion guidelines for combination medications.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	23 Feb 2021 12:47:57
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include all of the components (e.g. Medication Name = TRIUMEQ 600mg/50mg/300mg) and specify the # of tabs per eCRF completion guidelines for combination medications.' answered with 'updated record' (Site from DM).	Judith Martin (b) (4) (b) (4) Jennifer Nagg (b) (4) (b) (4)	19 Feb 2021 14:48:31 18 Feb 2021 18:59:34

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jennifer Nagg (b) (4)	18 Feb 2021 18:59:11
User entered '1.5' reason for change: Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	18 Feb 2021 18:59:11
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include all of the components (e.g. Medication Name = TRIUMEQ 600mg/50mg/300mg) and specify the # of tabs per eCRF completion guidelines for combination medications.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 07:36:37
	(b) (4), (b) (6)	17 Dec 2020 15:51:42
User closed query 'please update to 950 as noted in source. thank you' (Site from CRA).		17 Dec 2020 15:51:31
User closed query 'Per CDM: Site response noted; however, "Dose per administration" = "1" and "Dose unit" = "1 TABLET CONTAINS: 600 MG OF ABACAVIR, 50 MG OF DOLUTEGRAVIR, AND 300 MG OF LAMIVUDINE". Please update the dose unit to "mg" and the "Dose per administration" = "600/50/300". Please review and reconcile. Thank you.' (Site from DM).		15 Dec 2020 11:19:38
Query 'Per CDM: Site response noted; however, "Dose per administration" = "1" and "Dose unit" = "1 TABLET CONTAINS: 600 MG OF ABACAVIR, 50 MG OF DOLUTEGRAVIR, AND 300 MG OF LAMIVUDINE". Please update the dose unit to "mg" and the "Dose per administration" = "600/50/300". Please review and reconcile. Thank you.' answered with 'updated to 950' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 19:36:23
Query 'please update to 950 as noted in source. thank you' answered with 'updated to 950' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 19:36:13
User entered '950' reason for change: Data Entry Error		14 Dec 2020 19:36:01
User opened query 'please update to 950 as noted in source. thank you' (Site from CRA).		18 Nov 2020 16:10:30



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Site response noted; however, "Dose per administration" = "1" and "Dose unit" = "1 TABLET CONTAINS: 600 MG OF ABACAVIR, 50 MG OF DOLUTEGRAVIR, AND 300 MG OF LAMIVUDINE". Please update the dose unit to "mg" and the "Dose per administration" = "600/50/300". Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:18:58
User closed query 'Per DM CLR: Please note, this is a combination drug; however, the total component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 50/600/300).' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:18:58
User entered '1' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	15 Nov 2020 12:54:26
User entered '600 MG OF ABACAVIR, 50 MG OF DOLUTEGRAVIR, AND 300 MG OF LAMIVUDINE' (non-conformant).	Lalicia Roman (b) (4)	13 Nov 2020 19:08:32
Query 'Per DM CLR: Please note, this is a combination drug; however, the total component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 50/600/300).' ' answered with 'updated' ' (Site from DM).	Lalicia Roman (b) (4)	13 Nov 2020 16:41:16
DataPoint Un-verified.	Lalicia Roman (b) (4)	13 Nov 2020 16:39:49
User entered '600 mg of abacavir, 50 mg of dolutegravir, and 300 mg of lamivudine.' (non-conformant).	Lalicia Roman (b) (4)	13 Nov 2020 16:39:49
User opened query 'Per DM CLR: Please note, this is a combination drug; however, the total component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 50/600/300).' ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:18:51
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:45:36
User entered '950'	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:36:38
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:12:04
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 20:12:04
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Un-verified.	(b) (4) Jennifer Nagg (b) (4)	18 Feb 2021 18:59:11
User entered 'tablet (TABLET)' reason for change: Data Entry Error	(b) (4) Jennifer Nagg (b) (4)	18 Feb 2021 18:59:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:51:45
User closed query 'Please update Dose Unit to "mg" ' (Site from CRA).	(b) (4)	17 Dec 2020 15:51:35
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	14 Dec 2020 19:41:33
Query 'Please update Dose Unit to "mg" ' answered with 'updated to mg' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 19:36:39
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	14 Dec 2020 19:36:01
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 19:36:01
User opened query 'Please update Dose Unit to "mg" (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:08:28
DataPoint Un-verified.	Jennifer Nagg (b) (4)	15 Nov 2020 12:54:26
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) Jennifer Nagg (b) (4)	15 Nov 2020 12:54:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:45:43
User entered 'mg (mg)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4)	17 Dec 2020 15:51:37
DataPoint Un-verified.	(b) (4), (b) (6)	14 Dec 2020 19:41:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 19:41:33
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:08:32
DataPoint Un-verified.	Jennifer Nagg (b) (4)	15 Nov 2020 12:54:26
User entered '1 Tablet contains: 600 MG OF ABACAVIR, 50 MG OF DOLUTEGRAVIR, AND 300 MG OF LAMIVUDINE' reason for change:	Jennifer Nagg (b) (4)	15 Nov 2020 12:54:26
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:45:45
User entered empty.	Lalicia Roman (b) (4)	11 Sep 2020 14:52:25
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:45:50
User entered 'once daily (QD)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:45:52
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:45:53
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

US3802218

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:49:22**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:45:56
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:46:00
User entered 'UN UNK 2016'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:46:02
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:46:04
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:46:09
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:46:11
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:52:25

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:52:25

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:52:25

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:52:25

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
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)	04 Nov 2020 01:48:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 01:48:28
Data point term sent to Coder	System	04 Nov 2020 01:47:28
Coding entries removed.	Jennifer Nagg (b) (4)	04 Nov 2020 01:47:21
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:46:53
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)	11 Sep 2020 14:54:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 14:54:35
Data point term sent to Coder	System	11 Sep 2020 14:53:56
User entered 'lisinopril'	Lalicia Roman (b) (4)	11 Sep 2020 14:53:14



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:46:55
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:31:25
User closed query 'Hypertension is listed as the indication in source. please verify .' (Site from CRA).		10 Nov 2020 04:31:23
User closed query 'The Indication of Kidney Health is not listed in the Medical History Form. Please verify and reconcile.' (Site from CRA).		10 Nov 2020 04:31:21
Query 'The Indication of Kidney Health is not listed in the Medical History Form. Please verify and reconcile.' answered with 'Updated' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:47:36
Query 'Hypertension is listed as the indication in source. please verify .' answered with 'Done' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:47:29
User entered 'Hypertension' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:47:21
User opened query 'Hypertension is listed as the indication in source. please verify .' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 16:47:54
User opened query 'The Indication of Kidney Health is not listed in the Medical History Form. Please verify and reconcile.' (Site from CRA).		19 Oct 2020 03:18:23
User entered 'kidney health'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:02
User entered '5'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:04
User entered 'mg (mg)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:05
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:09
User entered 'once daily (QD)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:11
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:15
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:17
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:19
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:24
User entered 'I'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:26
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:28
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:30
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:53:14

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:53:14

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:53:14



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:53:14

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:55:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:55:39
Data point term sent to Coder	System	11 Sep 2020 14:55:00
User entered 'glimepiride'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:51
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:57
User closed query 'Diabetes Type 2 is not listed in Medical History form. Please verify and reconcile. ' (Site from CRA).		01 Nov 2020 15:18:49
Query 'Diabetes Type 2 is not listed in Medical History form. Please verify and reconcile. ' answered with 'diabetes type 2 is present on Med Hx' (Site from CRA).		21 Oct 2020 20:57:17
User opened query 'Diabetes Type 2 is not listed in Medical History form. Please verify and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 03:20:31
User entered 'diabetes type 2'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:48:59
User entered 'I'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:02
User entered 'mg (mg)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:05
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:07
User entered 'once daily (QD)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:10
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:12
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:17
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:19
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:25
User entered 'I'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:30
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:36
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:49:39
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:54:10



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:54:10

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:54:10

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:54:10

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 18:42:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 18:42:27
Data point term sent to Coder	System	03 Nov 2020 18:41:42
Coding entries removed.	Emily Dougherty (b) (4)	03 Nov 2020 18:41:37
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:50:33
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 14:56:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 14:56:46
Data point term sent to Coder	System	11 Sep 2020 14:56:08
User entered 'Tamsulosin'	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:50:35
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
User closed query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 05:17:37
		03 Nov 2020 18:48:46
Query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs.' answered with 'updated' (Site from DM).	Emily Dougherty (b) (4)	03 Nov 2020 18:41:42
User entered 'Enlarged PROSTATE' reason for change: Data Entry Error	Emily Dougherty (b) (4)	03 Nov 2020 18:41:37
User opened query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs.' (Site from DM). User entered 'prostate'	(b) (4), (b) (6)	18 Sep 2020 12:08:56
	Lalicia Roman (b) (4)	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:50:43
User entered '0.4'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:50:45
User entered 'mg (mg)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:50:53
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:50:55
User entered 'once daily (QD)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:50:59
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:51:02
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

US3802218

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:49:22**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:51:04
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:51:18
User entered 'UN UNK 2017'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:51:16
User entered '0'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:51:21
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:51:23
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

US3802218

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:51:26
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:55:27

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:55:27

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:55:27

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:55:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:31
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)	11 Sep 2020 14:56:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:56:46
Data point term sent to Coder	System	11 Sep 2020 14:56:11
User entered 'aspirin'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:12:16
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify ' (Site from DM).		18 Nov 2020 14:19:21
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify ' answered with 'updated ' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:42:58
DataPoint Un-verified.	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:42:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:42:46
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 02:33:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:07:34
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:36
User entered 'heart health'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:39
User entered '81'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:41
User entered 'mg (mg)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:43
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:45
User entered 'once daily (QD)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:50
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:48
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:52
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:53
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:54
User entered 'I'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:59
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:08:01
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:08:04
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:05

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:56:05

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:56:05

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:56:05

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:08:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:55:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:55:42
Data point term sent to Coder Coding entries removed.	System Emily Carney (b) (4)	29 Oct 2020 15:40:37 29 Oct 2020 15:40:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:37:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:37:41
Data point term sent to Coder Data point term sent to Coder User entered 'fenofibrate'	System System Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 15:36:25 11 Sep 2020 14:57:16 11 Sep 2020 14:56:45



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:08:39
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:14:23
User closed query 'Hypertriglyceride is not involved on the Medical History Form. "Hyper" not specified on the Conmed log in source. ' (Site from CRA).		16 Nov 2020 03:15:25
Query 'Hypertriglyceride is not involved on the Medical History Form. "Hyper" not specified on the Conmed log in source. ' answered with 'added' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:44:50
User opened query 'Hypertriglyceride is not involved on the Medical History Form. "Hyper" not specified on the Conmed log in source. ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:15:14
User closed query 'Indication of Triglycerides(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' (Site from CRA).		03 Nov 2020 17:15:14
Query 'Indication of Triglycerides(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' answered with 'updated' (Site from CRA).	Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:40:08
User entered 'HyperTRIGLYCERIDES' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:40:02
User opened query 'Indication of Triglycerides(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 03:31:32
User entered 'triglycerides'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:08:49
User entered '48'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:08:51
User entered 'mg (mg)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:08:54
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:08:56
User entered 'once daily (QD)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:08:57
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:08:59
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 15:35:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 15:35:44
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:35:44
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 14:56:45
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:09:00
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:09:02
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:09:05
User entered 'I'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:09:07
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:09:08
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:09:10
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	11 Sep 2020 14:56:45

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:56:45

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:56:45



US3802218

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 14:56:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 07:57:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 07:57:41
Data point term sent to Coder	System	11 Sep 2020 15:37:28
User entered 'VenlafaxineER'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:32
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:34
User closed query 'Anxiety is not listed in Medical History form. Please verify and reconcile. ' (Site from CRA).		01 Nov 2020 15:20:44
Query 'Anxiety is not listed in Medical History form. Please verify and reconcile. ' answered with 'anxiety listed on med hx' (Site from CRA).		21 Oct 2020 20:57:43
User opened query 'Anxiety is not listed in Medical History form. Please verify and reconcile. ' (Site from CRA).		19 Oct 2020 03:22:46
User entered 'Anxiety'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:39
User entered '150'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:41
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:23:10
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:45
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:47
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:50
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:51
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:53
User entered 'UN UNK 2016'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:56
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:22:58
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:23:03
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:16:08
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).		18 Nov 2020 14:19:30
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:43:17
DataPoint Un-verified.	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:43:12
User entered 'No (N)' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:43:12
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:21:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:23:04
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:36:46



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:36:46

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:36:46

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 15:36:46

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:23:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 07:57:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 07:57:42
Data point term sent to Coder	System	11 Sep 2020 15:38:30
User entered 'VenlafaxineER'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:23:55
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:23:57
User entered 'Anxiety'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:27:02
User entered '75'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:23:59
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:24:02
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:24:04
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:24:07
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:26:46
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:26:47
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:26:50
User entered 'UN UNK 2016'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:26:53
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:26:55
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:49:22**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:26:56
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:16:22
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).		18 Nov 2020 14:19:37
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:43:34
DataPoint Un-verified.	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:43:28
User entered 'No (N)' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:43:28
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:22:13
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:26:58
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:37:40

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:37:40

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:37:40

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 15:37:40

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 20:57:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:57:38
Data point term sent to Coder Coding entries removed.	System Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:45:40 04 Nov 2020 20:45:13
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:27:39
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)	11 Sep 2020 15:39:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:39:35
Data point term sent to Coder User entered 'Atorvastatin'	System Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:31 11 Sep 2020 15:38:27

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:27:40
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:49:45
User closed query 'Indication of Cholesterol(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' (Site from CRA).		09 Nov 2020 13:49:44
Query 'Indication of Cholesterol(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' answered with 'added' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:45:18
User entered 'High CHOLESTEROL' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:45:13
User opened query 'Indication of Cholesterol(hyper/Hypo) is not included in the Medical History form. Please verify and reconcile in the Medical History form.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 03:34:50
User entered 'Cholesterol'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:29:27
User entered '40'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:29:29
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:29:31
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:33:52
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:29:35
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:29:37
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:29:38
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:29:40
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:29:42
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:29:43
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:29:45
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 03:16:04
User closed query 'Please confirm if this medication was taken for a "solicited event" ' (Site from CRA).		16 Nov 2020 03:15:50
Query 'Please confirm if this medication was taken for a "solicited event" ' answered with 'not taken for solicited event' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:45:34
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:45:25
User opened query 'Please confirm if this medication was taken for a "solicited event" ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:36:38
DataPoint Un-verified.		03 Nov 2020 17:29:50
DataPoint Verified.		03 Nov 2020 17:29:47
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:38:27

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:38:27

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:38:27

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 15:38:27

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Dec 2020 22:36:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 22:36:49
Data point term sent to Coder	System	14 Dec 2020 19:41:18
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	14 Dec 2020 19:40:44
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'active ingredient added' (Site from System).	(b) (4), (b) (6)	14 Dec 2020 19:40:44
DataPoint Un-verified.		14 Dec 2020 19:40:25
User entered 'KENALOG OINTMENT 30g [triamcinolone acetonide]' reason for change: Per Query Resolution		14 Dec 2020 19:40:25
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:26:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:18:37
Data point term sent to Coder	System	13 Nov 2020 16:44:41
Data point term sent to Coder	System	04 Nov 2020 20:52:54
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	04 Nov 2020 20:52:35

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1863 of 2079



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'subject reported kenalog cream, uncertain of active ingredients' (Site from System).	Jennifer Nagg (b) (4)	04 Nov 2020 20:52:35
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	14 Sep 2020 09:31:38
Data point term sent to Coder	System	11 Sep 2020 15:40:38
User entered 'Kenalog Ointment'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:37:42
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:18:43
User closed query 'Per DM CLR: Please specify the location and type of Rash. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).		18 Nov 2020 14:20:04
Query 'Per DM CLR: Please specify the location and type of Rash. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'updated' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:44:40
DataPoint Un-verified.	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:44:33
User entered 'Generalized RASH' reason for change:	Lalicia Roman (b) (4)	13 Nov 2020 16:44:33
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please specify the location and type of Rash. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:37:45
User entered 'Rash'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
User closed query 'Per CDM re-query: Site response is noted. However, please update the Name of Medication field with KENALOG OINTMENT 30g. Also please update the specific dose and unit [e.g. 1 application (other), etc.] within the DOSE and UNIT fields. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:20:51
Query 'Per CDM re-query: Site response is noted. However, please update the Name of Medication field with KENALOG OINTMENT 30g. Also please update the specific dose and unit [e.g. 1 application (other), etc.] within the DOSE and UNIT fields. Thank you.' answered with 'updated' (Site from DM).		14 Dec 2020 22:05:59
DataPoint Un-verified.	(b) (4), (b) (6)	14 Dec 2020 22:05:51
User entered '1' reason for change: Data Entry Error		14 Dec 2020 22:05:51
User opened query 'Per CDM re-query: Site response is noted. However, please update the Name of Medication field with KENALOG OINTMENT 30g. Also please update the specific dose and unit [e.g. 1 application (other), etc.] within the DOSE and UNIT fields. Thank you.' (Site from DM).		22 Nov 2020 15:00:52
User closed query 'Per DM CLR: Please note, 30 g is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 1 application (Other), etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:00:52
Query 'Per DM CLR: Please note, 30 g is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 1 application (Other), etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate.' answered with 'Patient indicated the medication was 30g' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	13 Nov 2020 16:45:09

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, 30 g is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 1 application (Other), etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 02:43:03
	(b) (4), (b) (6)	03 Nov 2020 17:37:48
User entered '30'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 22:05:51
User entered 'Other (OTHER)' reason for change:	(b) (4), (b) (6)	14 Dec 2020 22:05:51
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:37:53
User entered 'g (g)'	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Un-verified.	(b) (4)	(b) (4)
User entered 'application' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 22:05:51
DataPoint Verified.		14 Dec 2020 22:05:51
		03 Nov 2020 17:38:38
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:39:48
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:42
User entered 'as needed (PRN)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:47
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:51
User entered 'Topical (TOPICAL)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:39:05
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:39:48
User entered 'UN UNK 2017'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:39:50
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:39:52
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:39:55
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:19:02
User closed query 'Please confirm response as "yes" to solicited event. thank you' (Site from CRA).		16 Nov 2020 03:16:21
Query 'Please confirm response as "yes" to solicited event. thank you' answered with 'updated' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:52:51
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:52:43
User opened query 'Please confirm response as "yes" to solicited event. thank you' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:49:39
DataPoint Un-verified.		03 Nov 2020 17:40:08
DataPoint Verified.		03 Nov 2020 17:40:07
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:39:48



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:39:48

US3802218

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:39:48

US3802218

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 15:39:48

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 08:45:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 08:45:44
Data point term sent to Coder	System	11 Sep 2020 15:41:43
User entered 'Levocetirizine'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:58
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:00
User entered 'Dust Allergies'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:50:02
User entered '5'	Dominic Kramer (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:50:03
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:50:05
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:50:08
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:50:09
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:50:11
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:50:13
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:50:14
User entered 'UN UNK 2015'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:50:16
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:50:17
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:50:20
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:20:02
User closed query 'Please confirm response to solicited event . ' (Site from CRA).		16 Nov 2020 03:16:33
Query 'Please confirm response to solicited event . ' answered with 'done' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:51:21
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:51:15
User opened query 'Please confirm response to solicited event . ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:51:06
DataPoint Un-verified.		03 Nov 2020 17:50:28
DataPoint Verified.		03 Nov 2020 17:50:22
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:40:45

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:40:45

US3802218

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:40:45

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 15:40:45

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:42:36
Data point term sent to Coder	System	11 Sep 2020 15:41:44
User entered 'Vitamin D3'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:20:42
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).		12 Nov 2020 05:22:57
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'done' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:49:40
DataPoint Un-verified.	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:49:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:49:35
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 02:31:50
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:28
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:20:49
DataPoint Un-verified.		18 Nov 2020 16:20:44
DataPoint Verified.		03 Nov 2020 17:53:45
User entered 'Supplement'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:20:51
DataPoint Un-verified.	Jennifer Nagg (b) (4)	04 Nov 2020 20:50:53
	(b) (4)	
User entered '2000' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	04 Nov 2020 20:50:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:54
User entered '50'	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:20:55
DataPoint Un-verified.	Jennifer Nagg (b) (4)	04 Nov 2020 20:50:53
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4) Jennifer Nagg (b) (4)	04 Nov 2020 20:50:53
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:59
User entered 'Other (OTHER)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:20:59
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).		05 Nov 2020 11:35:33
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'done' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:50:59
User entered empty; reason for change Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 20:50:53
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:30:36
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "mg" from the drop down list. Please update accordingly. Else Clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:30:30



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:55:05
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:55:07
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:55:08
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:55:10
User entered empty.	Dominic Kramer (b) (4)	11 Sep 2020 15:41:41



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:55:12
User entered 'UN UNK 2015'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:55:13
User entered '0'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:55:14
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:55:16
User entered empty.	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:55:19
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	11 Sep 2020 15:41:41

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:41:41

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 15:41:41

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 15:41:41



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:31:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:11:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:11:48
Data point term sent to Coder	System	04 Nov 2020 21:00:19
User entered 'heparin'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:31:47
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:31:51
User entered 'clot prevention'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:31:53
User entered '5000'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:31:57
User entered 'Other (OTHER)'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:56
User entered 'units'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:16
User entered 'three times daily (TID)'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:20
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:49:22**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:23
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:36
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:33:52
User entered '29 Oct 2020'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:49:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:28
User entered '0'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Un-verified.	(b) (4)	
	Jennifer Nagg (b) (4)	19 Jan 2021 12:38:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 12:38:05
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:26
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Un-verified.	(b) (4)	
	Jennifer Nagg (b) (4)	19 Jan 2021 12:38:05
User entered '5 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	19 Jan 2021 12:38:05
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:29
User entered empty.	Jennifer Nagg (b) (4)	04 Nov 2020 21:00:16
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:31
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 21:00:16

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User entered '3'	System	04 Nov 2020 21:00:16



**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User entered '1'	System	04 Nov 2020 21:00:16

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:17:35
User entered '804 (804)'	System	04 Nov 2020 21:00:16

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:54:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 14:55:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 14:55:51
Data point term sent to Coder	System	10 Mar 2021 14:54:33
DataPoint Un-verified.	Emily Carney (b) (4)	10 Mar 2021 14:54:09
Coding entries removed.	Emily Carney (b) (4)	10 Mar 2021 14:54:09
Signature has been broken.	Emily Carney (b) (4)	10 Mar 2021 14:54:09
User entered 'influenza VACCINE' reason for change: Data Entry Error	Emily Carney (b) (4)	10 Mar 2021 14:54:09
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:01:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:01:31
Data point term sent to Coder	System	12 Nov 2020 16:00:42
User entered 'Flu vaccine'	Emily Carney (b) (4)	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:08
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:10
User entered 'Prevent influenza infection'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:54:12
DataPoint Un-verified.	(b) (4)	
	Emily Carney (b) (4)	10 Mar 2021 14:54:09
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	10 Mar 2021 14:54:09
User entered '0.5' reason for change: Data Entry Error	(b) (4)	
	Emily Carney (b) (4)	10 Mar 2021 14:54:09
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:53:11
User entered 'Unk'	Emily Carney (b) (4)	12 Nov 2020 16:00:19
	(b) (4)	

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:13
User entered 'mL (mL)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:16
User entered empty.	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:18
User entered 'once (ONCE)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:19
User entered empty.	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:21
User entered 'Intramuscular (INTRAMUSCULAR)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:23
User entered empty.	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:25
User entered '6 Nov 2020'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:28
User entered '0'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:30
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:49:22**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:31
User entered '6 Nov 2020'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19



US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:53:33
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:19

**US3802218**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:49:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User entered empty.	System	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User entered empty.	System	12 Nov 2020 16:00:19

US3802218

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:49:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:34
User entered empty.	System	12 Nov 2020 16:00:19

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:49:22

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:24
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:01:11
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:00:53

US3802218

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:03:50
User entered '30 Oct 2020'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:02:34

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:49:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: PARAESOPHAGEALÂ HERNIA REPAIR - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:19:05
Query 'Per CDM: PARAESOPHAGEALÂ HERNIA REPAIR - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' answered with 'The indication has been updated to AE because although the participant had the hernia at enrollment, the worsening caused the need for surgery and thus it has been updated to match. ' (Site from DM).	Emily Carney (b) (4) (b) (4)	31 Mar 2021 16:15:45
User opened query 'Per CDM: PARAESOPHAGEALÂ HERNIA REPAIR - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:47:46
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:03:50
User entered 'paraesophageal hernia repair'	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:02:34

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:50:40
	(b) (4)	
DataPoint Un-verified.	Emily Carney (b) (4)	31 Mar 2021 16:14:47
	(b) (4)	
Signature has been broken.	Emily Carney (b) (4)	31 Mar 2021 16:14:47
	(b) (4)	
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Emily Carney (b) (4)	31 Mar 2021 16:14:47
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:03:50
User entered 'Medical History (MH)'	Emily Carney (b) (4)	12 Nov 2020 16:02:34
	(b) (4)	



US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:49:22

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:03:50
User entered empty.	Emily Carney (b) (4) (b) (4)	12 Nov 2020 16:02:34

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:49:22

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:51
User signature succeeded.	Judith Martin (b) (4)	05 Mar 2021 20:23:23
User closed query 'Per DM CLR: Please review if this Con Proc was done for AE #1 PARAESOPHOGEAL HIATAL HERNIA WORSENING (28 OCT 2020-05 NOV 2020). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:43:51
Query 'Per DM CLR: Please review if this Con Proc was done for AE #1 PARAESOPHOGEAL HIATAL HERNIA WORSENING (28 OCT 2020-05 NOV 2020). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' answered with 'Entry error, updated date ' (Site from DM).	Emily Carney (b) (4) (b) (4)	03 Mar 2021 16:07:08
Signature has been broken.	Emily Carney (b) (4) (b) (4)	03 Mar 2021 16:06:51
User entered '30 Oct 2020' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	03 Mar 2021 16:06:51
User opened query 'Per DM CLR: Please review if this Con Proc was done for AE #1 PARAESOPHOGEAL HIATAL HERNIA WORSENING (28 OCT 2020-05 NOV 2020). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 10:23:52
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34

US3802218

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:49:22**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Dec 2020'	Jennifer Nagg (b) (4) (b) (4)	19 Jan 2021 12:44:47

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:49:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:51
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'LEFT PIGTAIL CATHETER'	(b) (4) Jennifer Nagg (b) (4)	19 Jan 2021 12:44:47

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:51
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Nagg (b) (4)	19 Jan 2021 12:44:47

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:49:22

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:51
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Jan 2021 12:44:47

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:49:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '28 Oct 2020'	(b) (4) Jennifer Nagg (b) (4)	19 Jan 2021 12:46:16

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:49:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 14:07:34
User entered 'CXR'	Jennifer Nagg (b) (4) (b) (4)	19 Jan 2021 12:46:16



US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Nagg (b) (4)	19 Jan 2021 12:46:16

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:49:22

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Jan 2021 12:46:16
	(b) (4)	

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:49:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered '31 Oct 2020'	(b) (4) Jennifer Nagg (b) (4)	19 Jan 2021 12:46:36

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:49:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'CXR'	(b) (4) Jennifer Nagg (b) (4)	19 Jan 2021 12:46:36

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:49:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Nagg (b) (4)	19 Jan 2021 12:46:36

US3802218

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:49:22

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:01:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	19 Jan 2021 12:46:36

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:40
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:03
User entered '5'	System	19 Feb 2021 15:03:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
	(b) (4)	
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:40
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:03
User entered '5'	System	19 Feb 2021 15:03:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
	(b) (4)	
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:49:22**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
User entered '03/Nov/2020 17:24'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:49:22

**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.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		11 Nov 2020 15:51:07
User entered 'I'		03 Nov 2020 17:24:23



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:40
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:03
User entered '5'	System	19 Feb 2021 15:03:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
	(b) (4)	
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:49:22**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
User entered '11/Nov/2020 15:51'	System	11 Nov 2020 15:51:19

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:49:22

**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.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		12 Nov 2020 12:53:13
User entered 'I'		11 Nov 2020 15:51:19

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09



US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09



US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:40
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:03
User entered '5'	System	19 Feb 2021 15:03:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
	(b) (4)	
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:49:22**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
User entered '12/Nov/2020 07:53'	System	12 Nov 2020 12:53:22

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:49:22

**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.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		16 Nov 2020 14:54:55
User entered 'I'		12 Nov 2020 12:53:22

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:40
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:03
User entered '5'	System	19 Feb 2021 15:03:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
	(b) (4)	
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:49:22**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
User entered '16/Nov/2020 09:55'	System	16 Nov 2020 14:55:04

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:49:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 15:02:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
User entered 'I'		16 Nov 2020 14:55:04

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'USA-US098-2020-MRNA-1273-P301000001'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Yes (Y)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'No (N)'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Judith'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'Martin'	System	03 Nov 2020 17:23:09



**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '3420 Fifth Ave'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 17:24:16
User entered 'Pittsburgh'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered 'PA'	System	03 Nov 2020 17:23:09

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:49:22**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		03 Nov 2020 17:24:16
User entered '15213'	System	03 Nov 2020 17:23:09

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:54
Reviewed for Safety.		11 Nov 2020 15:51:07
User entered 'US'	System	03 Nov 2020 17:24:23

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:40
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:03:03
User entered '5'	System	19 Feb 2021 15:03:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 14:07:34
	(b) (4)	
User entered '4'	System	16 Nov 2020 14:55:04
User entered '3'	System	12 Nov 2020 12:53:22
User entered '2'	System	11 Nov 2020 15:51:19
User entered '1'	System	03 Nov 2020 17:24:23

**US3802218**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:49:22**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 16:30:40
User entered '19/Feb/2021 09:03'	(b) (4) System	19 Feb 2021 15:03:03

US3802218

Folder: SAE USA-US098-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:49:22

**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.	Judith Martin (b) (4)	19 Feb 2021 16:30:40
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:03:03